# A STUDY ON
# KUMBA VATHAM
## *(Periarthritis)*

***Dissertation Submitted To***

**THE TAMIL NADU Dr. M.G.R. Medical University**

**Chennai – 32**

*For the Partial fulfillment for the Award of Degree of*

**DOCTOR OF MEDICINE (SIDDHA)**

**(Branch – III, SIRAPPU MARUTHUVAM)**


**DEPARTMENT OF SIRAPPU MARUTHUVAM**

**Government Siddha Medical College**

**Palayamkottai – 627 002.**

**OCTOBER - 2018**

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I hereby declare that this dissertation entitled **"A STUDY ON KUMBA VATHAM"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. M. AHAMED MOHIDEEN., M.D(s).,** Associate Professor PG - III - Department of Sirappu Maruthuvam, Govt. Siddha Medical College, Palayamkottai and the dissertation has formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

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### INGREDIENTS OF SANTHIRA PRAGASA MATHIRAI

| S.NO | DRUGS | BOTANICAL NAME | FAMILY | PART USED |
|---|---|---|---|---|
| 1. | Milagu | Piper nigrum | Piperaceae | Unriped fruit |
| 2. | Purified naabi | Aconitum napellus | Ranunculaceae | Root |
| 3. | Inji | Zingiber officinale | Zingiberaceae | Rhizome |

### INGREDIENTS OF SEMBAI THYLAM

| S.NO | DRUGS | BOTANICAL NAME | FAMILY | PART USED |
|---|---|---|---|---|
| 1. | Karunsembai | Sesbania sesban | fabaceae | Leaf |
| 2. | Vellulli | Allium sativum | Liliaceae | Bulb |
| 3. | Palingu sampirani | Styrax benzion | Styracaceae | Resin |
| 4. | Diccamalli | Gardenia gummifera | Rubiaceae | Pisin |

Station:

Date:

Authorized signature

Dr. S. SUTHA, M.Sc.,M.Ed.,Ph.D.,
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**INGREDIENTS OF SANTHIRA PRAGASA MATHIRAI**

| S.NO | TAMIL NAME | ENGLISH NAME |
|---|---|---|
| 1. | Vengaaram | Borax |

Station: palayamkottai

Date: 14.06.17.

Authorized signature 14/06/17

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## CERTIFICATE OF APPROVAL

| | |
|---|---|
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| Principal investigator | Dr.M.Shanmuga priya.<br>I Year, PG Dept of Sirappu Maruthuvam<br>Reg.No : |
| Guide | Dr.M.Ahamed mohideen.M.D(s)<br>Reader<br>Dept of sirappu maruthuvam |
| Dissertation topic | An open clinical Study to evaluate the clinical efficacy of siddha sasthric formulation "**SANTHIRAPRAGASAMATHIRAI**"(Internal)"SEMBAI THYLAM "for the treatment of **KUMBA VATHAM**. |
| Document field | 1. Protocol2. Date Collection Form<br>3. Patient Information Sheet<br>4. Consent form5. SAE (Pharmacovigilance) |
| Clinical / Non Clinical trial Protocol | Clinical trial protocol – Yes |
| Informed consent document | Yes |
| Any other document | Case sheet, Investigation document |
| Date of IEC approval & it's Number | GSMC/3.IEC/2016/III-27/20.07.16 |

We approve the trial to be conducted in its presented form.

The Institutional Ethical committee expects to be informed about the process report to be submitted to the IEC at least annually of the study, any SAE occurring in the course of the study and changes in the protocol and submission of final report.

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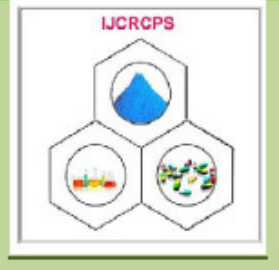


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# INTRODUCTION

Siddha system of medicine is a divine system medicine. It is distinguish from other Indian medicine because it is based on 96 philosophes. siddha medicine is created by 18 intellectual siddhars. they have well Knowledge about astanga yogam and panchapootha theory.

siddha medicine not only cures the disease but also it rejuvenate the body. The three humors (vatham, pitham, kabam) play a major role in causing the diseases. the diseases in siddha are classified into 4448.

**Kuthambai Siddhar says,**

**"முப்பிணிதனை அறியாத மூடர்கள்**
**எப்பிணி தீர்ப்பாரடி - குதம்பாய்**
**எப்பிணி தீர்ப்பாரடி நாடியொருபது நன்காய நிந்திடில்**
**ஓடிவிடும் பிணியே - குதம்பாய்**
**ஓடிவிடும் பிணியே**
**சுத்த வகை தாது தன்னையறிந்தோர்**
**சுத்த வைத்தியனே - குதம்பாய் சுத்த வைத்தியனே**
**வாயுவொரு பத்தும் வாய்ந்த நிலைகணடோர்**
**ஆயுள் அறிவானடி - குதம்பாய்**
**ஆயுள் அறிவானடி"**

According to Yugi vaithiya chinthamani vatha disease are categarisezed into 80 types. Among them Kumba vatham is one of the vatha disease. The symptoms of Kumba vatham that given in YUGI VAITHIYA CHINDAMANI 800 is mostly correlated with the symptoms of periarthrities of shoulder.

Arthritis of shoulder is a kind of chronic inflammation caused by the strain and anaplasia of the parenchyma including muscle, ligament, tendon, joint capsule etc, which is clinically manifested by painful shoulder and limited movements.

The prevalence of the disease is approximately 3% in the general population. Occurrence is rare in children & peaks between 40-70 yrs of age common in diabetics and in women.

The clinical manifestation mainly represent as generally pain and tenderness of the shoulder (especially abduction, external rotation and post extend are extremely restricted) further more the pain exacerbates at night and the atrophy and accretion of the muscle around the shoulder are obvious after a period of time.

Shoulder joint is the widest range of motion of the body, so it is easy to fatigue and injury in the daily living and muscle easier to induce the diseases.

The morbid change in periarthritis of the shoulder may affect the joint capsule, or the periarticular soft tissue, especially the subacromial bursa, the sheath of the long head of the biceps and the supra spinatus tendon. Having chronic inflammation, fibrotic & degenerative process.

It can be diagnosed by limits to the active and passive range of motion. An arthogram or an MRI may confirm the diagnosis, though in practice this is rarely required.

There is no proper medication in other system of medicine. In modem seience they have to use NSAIDS and intra articular (IA injection)

In chronic use of the above drug is more abundance and have prospected Complications like renal failure, psycological effects etc. so the community is looking for treatment which is cost effectivefree from side effects and the one which provide good relief from the disease.increased prevalence of the disease and the dreadfull effect caused by the disease calculating a suitable treatment for the disease.

Santhira pragasa Mathirai(Internal) with chukku kudineer and Sembai Thylam (external) have been taken as the trial medicine .this medicines are also mentioned in siddha sastric literature. The internal medicine Santhira pragasa Mathirai is one of the herbo- mineral formulation. The incredients in the Sembai thylam which is used for external application have Anti vatha property. So the Author select these medicines as a trial drugs for the treatment of kumbavatham.

Massage and fomentation are the best external therapies used in Sirappu maruthuvam branch to cure the vatha disease.So I have select these therapies as a coplementory therapy along with the trail drug.

The trial drugs were prepared by the author and were tried in 40 cases of kumba vatham of varied aetiology and the clinical study was undertaken in the Post graduate department of sirappu maruthuvam OP and IP. and the follow up study of all the cases was done in the post graduate out patient.

# AIM AND OBJECTIVE

**AIM:**

To evaluate the clinical efficacy of "**SANTHIRA PRAGASA MATHIRAI"** (internal) and "**SEMBAI THYLAM**"(external) for the treatment of **KUMBA VATHAM** (PERI ARTHRITIS).

**Primary objective** :

To evaluate the clinical efficacy of "**SANTHIRA PRAGASA MATHIRAI"** (internal) and "**SEMBAI THYLAM**"(external) for the treatment of **KUMBA VATHAM** (PERIARTHRITIS).

**Secondary objective:**

- To study the Siddha basic principles like envagai thervukkal including neerkkuri and neikkuri.
- To evaluate the safety profile of the trial medicine.
- To Evaluate the pharmacological study of trial medicine

# REVIEW OF LITERATURE
## SIDDHA ASPECT

### KUMBA VATHAM

**Definition**

Kumba vatham is a condition the involvement of painful restricted movement of the shoulder joint. A kind of arthritis attended with boring pain in the shoulders and arms, restricted movements of upper limb.

**Clinical features of kumba vatham.**

"நவிலவே தோண்மீதுங் கரத்தின் மீது
நலிந்து மெத்த வாதியே நசவுண் டாகும்
கவிலவே கன்னமொடு நயனந் தானுங்
கடுத்துமே விறுவிறுப்பு மெரிவுங் காணும்
துவிலவே துடிப்பாகுஞ் சிரசு தன்னிற்
சுழற்றியே நாபிக்கீழ் வலியு முண்டாம்
அவிலவே யடிநாக்கி லழன்று காணு
மலருமே வருகும்ப வாதந் தானே."

**பொருள்**

தோட்பட்டை, கை முதலிய இடங்களில் மிக்க நோயுண்டாகி அவைகளை நீட்டவும் முடக்கவும் ஒட்டாமல் நோதலும், கன்னமும் கண்ணும் கடுத்து விறுவிறுத்து எரிதலும், உடல் துடித்துத் தலை சுற்றி மிகு சுரமுண்டாய் நாவின்கீழ் வலியும், அடிநாக்கில் அழற்சியும் ஆகிய குறி குணங்கள் இந்நோயிற் காணும்.

**Aetiology**

Yugi munivar summarized 80 type of vatha disease. He is mention's various factors for the cause of vatha disease as follows which includes various intrinsic and extrinsic factors.

"தானென்ற கசப்போடு துவர்ப்பு றைப்பு
சாதகமாய் மிஞ்சுகிலும் சமைத்த வன்னம்
ஆனென்ற அறிவது புசித்த லாலும்
ஆகாயத் தேறலது குடித்த லாலும்
பானென்ற பகலுறக்க மிராவிழிப்பு
பட்டினியே மிகவுறுதல் பார மெய்தல்
தேனென்ற மொழியாற் மேற்சிந்தை யாதல்
சீக்கிரமாய் வாதமது செவிக்குந் தானே"

- யூகி சிந்தாமணி

Intake of excess in bitter, astringent and pungent taste, intake of old cooked food items, drinking rain water, sleeping during day time and awakening at night, long duration starvation, strain due to excessive weight lifting and sexual perversion.

“வாதவர்த் தனைகால மேதோ வென்னில்
மருவுகின்ற வானிகர்க் கடகமாகும்
ஆதவைப் பசியோடு கார்த்திகை தன்னில்
அடருமே மற்றமா தங்கள் தன்னில்
போதவே சமிக்குகின்ற காலமாகும்.”

- யூகிசிந்தாமணி

The disease mostly seen in Aani to Karthikai

“‘ஆனான வரன்றனையே மதியா மாந்தர்
அகதி பரதேசியர்கட்கன்ன மீயார்
கோனான குருமொழியை மறந்த பேர்கள்
கொலைகளவு பொய்காமங் குறித்த பேர்கு
ஊனான சடந்தன்னில் வாதம் வந்து
உற்பணிக்கும் வேதத்தணுண்மைதானே.”

- யூகி சிந்தாமணி

Forgetting the advice of preceptors and mudering people, stealing, speaking lie and involving in immoral activities.

“‘பகரவே வாதமலு கோபித் தப்போ
பண்பாகப் பெண்போக மதுதான் செய்யில்
நகரவே வெகுதூர வழிந டக்கில்
நளிரான காற்றுமே பனி மேற்பட்டால்
மிகரவே காய்கள் கனி கிழங்கு தன்னை
மிகவருந்தி மீறியே தயிர்தான் கொண்டால்
முகரவே முதுகெலும்பை முறுக்கி நொந்து
முழங்காலும் கணைக்காலும் கடுப்புண்டாமே.

- யூகி சிந்தாமணி

Indulging in the sexual act during vitiation of vatha, walking for a long distance, exposing to cold and dampness, intake of excessive curd after eating fruits, tubers and vegetables causes toxic factors which affects bones and muscles.

**Vatha kanma varalaru**

“‘நூலென்ற வாதம் வந்த வகைதானேது
துண்மையாய் கன்மத்தின் வகையைக்
காலிலேதோன்றியது கடுப்பதேது

கைகாலில் முடக்கியது வீக்கமேது
கோலிலே படுக்கின்ற விருட்சமான
குழந்தை மரந்தனை வெட்டல் மேல்தோல்
நாளிலே சீவசெந்து கால் றறித்தல்
நல்லகொம்பு தழை முறித்தல் நலித்தல் காணே."

- அகத்தியர் கன்மகாண்டம்

The following psychosocial factors such as removing the bark of living trees, breaking the legs of animals, cut the leaves and branches of the tree.

**To sum up**

The following intrinsic and extrinsic factors are attributed to be the causative factors for the manifestation of vatha diseases.

**Intrinsic factors**

**Dietic**

- Excess intake of bitter, astringent and pungent taste
- Excess intake like curd after eating fruits, vegetable and tuber and starving

**Psycho social aspects**

- Forgetting the advice of preceptors and wickedness such as murdering
- Stealing
- Truthless speech
- Involving in immoral activities
- Spoiling the chastity of a woman
- Abusing the holy men and ritualists
- Ingratitude towards mother, father and teacher.
- Refusing the food for destitudes and sannyasins.
- Cutting the trees, leaves and branches.
- Breaking the legs of the animal

**Extrinsic factors**

- Physical strain due to excessive weight lifting
- Sleeping during day time and awakening at night
- Improper food habits that increasing vatham.
- Exposure to dampness and cold
- Precipitation of the disease in the months from Aani to karthigai
- Walking for a long distance.

**Patho physiology**

According to panchapootha principle when elemental composition of altered naturally uyir thathugal or the three humours, which are made up of these elements get deranged. This simultaneously lead to derangement of seven udal thathugal which produce symptoms. This is one way of pathology, producing kumba vatham.

Another theory which explains as follows, the etiological factors of kumbavatham are both diet that produce excessive vayu and other agents which cause vitation of vayu aahayam, earth and fire, depending upon this corresponding uyir thathu is affected.

Here:

| | | |
|---|---|---|
| Aahayam + Air | - | Vatham |
| Earth + Water | - | Kabam |
| Fire | - | Pitham |

Vatham, pitham and kabam are deranged simultaneously udal thathugal get deranged.

**ஐம்பூதம் தேகத்திற்கு உள்ள ஒற்றுமையாவன**

"அண்டத்தில் உள்ளதே பிண்டம்
பிண்டத்தில் உள்ளதே அண்டம்
அண்டமும் பிண்டமும் ஒன்றே
அறிந்துதான் பார்க்கும் போதே"

- சட்டமுனி

பிரபஞ்சம் ஐம்பூதமயமானது. தோன்றி, நிலைத்து, அழிந்து அப்பால் மறுபடியும் தோன்றி நிலைத்து அழிந்து போகும் பொருட்கள் யாவும் ஓரிடத்தில் ஒடுங்கும். இதுவே பரப்பிரம்மம் என்பர். தோன்றும்போதும் அவ்விடத்திலிருந்தே படைத்தல், காத்தல், அழித்தல் என்னும் சக்திகளுக்கிணங்க நிகழும் இவ்வுலகம் ஐம்பூதமயமானது என்பர். தேகமும் ஐம்பூதக் கொள்கைக்கு விலக்கில்லை.

"நிலம் நீர்தீவளி விசும்போடைந்தும்
கலந்தமயக் கமுலகம் இது"

- நோய்நாடல் நோய்முதல்நாடல் பகுதி

**1. Earth (நிலம்)**

- Gives shape to the body and release its energy.
- Bones, muscles and tissues represent it in the body.

**2. Water (நீர்)**

- Makes the earth supple and helps in the transmission of energy, serum, lymph, saliva etc.
- Represent it in the body.

**3. Fire (தீ)**

- Steadies the form of the body and gives vigour and stimulation
- Digestion and circulation represent it in the body.

**4. Air (வளி)**

- Ignites the fire and works as a life carrier and its he support of all contact and exchange
- Respiration and nervous system represent in the body.

**5. Ether (விசம்பு)**

- Ether is the creater of life itself in the body.
- A harmonious, cambination and function of these five elements in the body produce a healthy and beautiful life.
- Man has gross physical body and subtle physical body is immediately behind the gross physical body and is closely connected with it.

Vatham = Air + Ether

In kumba vatham both air and ether are affected

- The life-force which is different from material energy derived from food, pervades the gross physical through the subtle physical.

**ஐம்பூதங்கட்கும், அறுசுவைகளுக்கு முள்ள ஒற்றுமையாவன:**

"மண்ணுடனே புனல் தீக்கால்
முறையாகச் சேர்ந்திட்டால் வருமே இனிப்பு
திண்ணமிலம் துவர்ப்பிரசம்
சதாகதியோ டார்தீவிண் திடமா முறைப்பும்
எண்ணரிய கசப்பு முண்டாற்
தண்ணீரில் கனவிணைப்பா லெழுமா முவர்ப்பு
உண்ணரிய அறுசுவையின்
பிறப்பிதெனும் குருசித்தருரைத்த மறையே"

- தோற்றக்கிரம ஆராய்ச்சியும், சித்தமருத்துவ வரலாறும்.

இனிப்பு - பிருத்வி + அப்பு

புளிப்பு - பிருத்வி + தேயு

உவர்ப்பு - அப்பு + தேயு

கைப்பு - வாயு + ஆகாயம்

கார்ப்பு - தேயு + வாயு

துவர்ப்பு - பிருத்வி + அப்பு

இச்சுவைகளின் மிகுதியைக் கொண்டு, தேகத்தில் எப்பூதங்களினளவாக எக்குற்றங்கள் பிணிக்கப்பட்டிருக்கின்றன என்பதை அறியலாம்.

**கும்பவாதத்தில்**

கைப்பு, கார்ப்பு, துவர்ப்பு ஆகிய சுவைகள் பாதிக்கப்படுவதால் அதற்கு காரணமான பூதங்களும் பாதிக்கப்படுகின்றன.

**ஐம்பூதம் - முக்குற்றத்திற்கு முள்ள ஒற்றுமை**

வளி - வளி + விண்

அழல் - தீ

ஐயம் - நீர் + மண்

இரண்டிரண்டு பூதங்களின் சேர்க்கையால் உயிர்தாது உண்டாகிறது.

பூதங்கள் பாதிக்கட்படும் போது உயிர்த்தாதுக்கள் பாதிக்கப்படுகிறது.

**Vatham**

- Represents vayu
- Pain flatulence
- Sensitiveness
- Dryness
- Lightness and also air

**Pitham**

- Represents gastric juice
- Bile
- Energy
- Heat
- Inflammation
- Anger and irritation etc

**Kabam**

- Heaviness running of the nose
- Passing of mucoid discharge and also the saliva
- Represents feeling of cold.

## Diagnosis

சித்த மருத்துவ அடிப்படையில் நோய் கணிப்பில் எண்வகைத் தேர்வு முதன்மையானது.

மற்ற தேர்வுகளாவன.

- பொறியாற்றேர்தல்
- புலனாறிதல்
- வினாவுதல்
- உயிர்தாதுக்கள்
- உடல் தாதுக்கள்
- ஞானேந்திரியம்
- கன்மேந்திரியம்
- திணைகள்
- பருவகாலம்

**பொறியாற்றேர்தல்**

1. மூக்கு
2. நா
3. கண்
4. தோல்
5. செவி

மருத்துவர் ஐம்பொறிகளைக் கொண்டு நோயை கணிக்கமுடியும். கும்பவாதத்தில் கண் கடுத்து விறுவிறுத்து எரிதலும், அடிநாக்கில் அழற்சியும் காணப்படும். எனவே ஐம்பொறியில் கண், நா பாதிக்கப்படுகிறது.

**2. புலனாறிதல்**

1. நாற்றம் (மணம்)
2. சுவை
3. ஒளி
4. ஊறு
5. ஓசை

மருத்துவர் ஐம்புலன்களைக் கொண்டு நோயை கணிக்கமுடியும்.

**கும்பவாதத்தில்**

தோட்பட்டை, கை முதலிய இடங்களில் மிக்க நோயுண்டாகி அவைகளை நீட்டவும்

முடக்கவும் ஒட்டாமல் நோதலும், கன்னமும் கடுத்து விறுவிறுத்து எரிதல் உள்ளதால் ஐம்புலன்களில் ஊறு பாதிக்கப்பட்டுள்ளது.

**3. வினாவுதல்**

மருத்துவர் நோயாளியிடம் வினாவுதல் மூலம் நோயை கணிக்கமுடியும். நோயாளியால் பேச முடியாத நேரத்தில் அவன் சுற்றத்தாரிடமும் வினாவுதல் மூலம் நோயை கணிக்கமுடியும்.

**எண்வகைத்தேர்வு**

"நாடிப்பரிசம் நாநிறம் மொழிவிழி
மலம் மூத்திரமிவை மருத்துவ ராயுதம்"

- நோய்நாடல் நோய் முதல் நாடல் பகுதி

"மெய்க்குறி நிறந்தொனி விழி நாவிருமலம் கைக்குறி"

- தேரையர்

1. நாடி
2. ஸ்பரிசம்
3. நா
4. நிறம்
5. மொழி
6. விழி
7. மலம்
8. மூத்திரம்

**Nadi**

Literally the following indications of Nadi are suggestive of pain in the body, pain in the joints difficulty in mobility, constipation, pain in the extremities and weakness in the extremities.

**வாத நாடி**

"வாதமெனும் நாடியது தோன்றில்
சீதமந்தமொடு வயிறுபொருமல் திரட்சிவாயு
சீதமுறுங்கிராணி மகோதரம் நீராமை
திரள்வாய்வு சூலை வலி கடுப்புத்திரை"

- சதகநாடி

கும்பவாதத்தில்,

1. வாத பித்தம்
2. வாத கபம்
3. கப வாதம்
4. கப பித்தம்

"வாதத்தில் குணமே தென்னில் வயிறது போருமிக்கொள்ளும்
தாதத்தில் மேனி கைகாலசந்துமே கடுப்புத் தோன்றும்.

- குறியடையாளநாடி

The patients have symptoms like pain the upper and lower extremities which cause alteration in vatha nadi.

**Vatha pitha Nadi**

"பொருளான வாதத்தில் பித்தஞ் சேர்ந்து
பொருந்து குணங்களா முஷ்ணவாயு சக்தி
செரியாமை புளித்தேப்பம் பொருமல் நீரிற்
சிவப்புமலம் பிரித்தலுருந் தாதுநட்டம்
கருவான தேகமதி லுளைச்சல் சோம்பல்
கைகால் தறிப்புநாக் கசக்கு மன்னம்"

- சதகநாடி

"எண்ணியவாதம் ரெண்டும் பித்த மென்றெழுந்தான்
புண்ணெனவுடம்பு நோவாம்"

- திரட்டுநாடி

The patients have joint disorders there is alteration in vathapitha naadi.

**Vatha kaba nadi**

"பாங்கான வாதத்தில் சேத்தும நாடிப்
பரிசித்தால் திமிர்மேவு முளைச்சலாகும்
தீங்கான இருமலுடன் சந்நி தோடம்
சேர்ந்தவிடம் வெடிசூலை இருத்ரோகம்
வாங்காத ஈளைமந் தார காசம்"

- சதகநாடி

"மான நோய் வாதம் ரெண்டும்
சிலேற்பன மொன் றெழுந்த தாகில்
ஆனதோர் சரீரநாவுங் கைகால் திமிர்த்துக் காட்டும்."

- திரட்டுநாடி

If there is alteration in the vatha kabha naadi, when the patient have spastic pain and weakness in the upper limb and lower limb.

**Kaba vatha nadi**

"கண்டாயோ சிலேற்பனத்தில் வாதநாடி
கலந்திடுகில் வயிறு பொருமல் கனத்த வீக்கம்
உண்டாலோ ஓங்காரஞ் சத்தி விக்கல்
உறுதிரட்சை வாய்வுவலி சந்நி தோடம்"

- சதகநாடி

“வாட்பிடுஞ் சேத்துமத்தில் வந்திடும் வாதமாகில்
நாட்டியகால்கள் போல நரம்பெல்லாம் வலித்து நிற்கும்
கூட்டிய பிடரிதாணுங் குன்றவே வலிக்கு மாகில
நாட்டிய விழியுமேலாய் நாவது குளறுந் தானே”

- அகத்தியர் நாடி

**Kaba Pitha Nadi**

“இடமான சேத்துமத்தில் பித்தநாடி
எழுந்தணுகில் விடமுடனே வீக்க முண்டாம்
திடமான குளிர்காய்ச்சல் மஞ்சள் நோவுத்
தேகத்தி லுளைச்சலிளைப் பிருமல் வாந்தி”

- சதகநாடி

**2. ஸ்பரிசம் (தொட்டுப்பார்த்தல்)**

உடல் வெப்பநிலை, சுரசுரப்பு, தோல் உலர்ந்திருத்தல், தேமல், கொப்பளம், கட்டிகள், கழலை, சொறி, சிரங்கு, படைவிரணம், வீக்கம், ஊதல் ஆகியவை தொட்டுப்பார்த்தல் மூலம் அறியலாம்.

In Kumba vatham patients the sparisam is normal.

**3. நா**

- மாப்படிந்திருந்தல், வெளுத்திருத்தல்
- வாய்நீர் வறண்டிருத்தல்
- பிளவு பட்டிருத்தல்
- புண்ணாயிருத்தல்
- சுவை மாறுபாடு

கும்பவாதத்தில் அடிநாக்கில் அழற்சி காணப்படுவதால் நா பாதிக்கப்படுகிறது.

**4. நிறம்**

- தோல்நிறம்
- சளிச்சவ்வு
- மயிர் மற்றும் நகம் முதலியவற்றின் நிறம்

In kumba vatham patients skin colour is normal.

**5. மொழி**

- ஒலி வேறுபாடு
- பிதற்றல் குளறல்
- குரல் கம்மிய பேச்சு

In Kumba vatham patients, no change of voice is present.

**6.கண்**

- கண் பார்வையின் நிலைமை
- கண் சிவந்திருத்தல், வெளுத்திருத்தல்
- கண் எரிச்சல்

In kumba vatham patients, burning sensation of eyes is present.

**7. மலம்**

- மலம் என்பது உடலினின்றும் கழிகின்ற பொருள்
- நிறம் - நுரை
- இறுகல், இளகல்
- மலக்கட்டு

In kumba vatham patients, malam is normal

**8.மூத்திரம்**

- நீர்க்குறி
- நெய்க்குறி

**நீர்க்குறி**

"அருந்துமாறி ரதமும் அவிரோதமாய்
அ.ˑ.கல் அலர்தல் அகாலவூன் தவிர்ந்தழற்
குற்றள வருந்தி உறங்கி வைகறை
ஆடிக் கலசத் தாவியே காதுபெய்
தொரு முகூர்த்தக் கலைக்குட்படு நீரின்
நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே"

- நோய்நாடல் நோய்முதல்நாடல் பகுதி

உண்ணுகின்ற அறுசுவைப் பொருள்களும் ஒன்றுக்கொன்று வேற்றுமையடையாமலும், பசிக்குத் தக்கபடி குறைதல், அதிகரித்தல் காலந்தவறி உண்ணுதல் முதலிய குற்றங்களுண்டாகா வண்ணம் புசித்து உறங்கி, விடியற்காலத்தில் படிக பாத்திரத்தில் பெய்த நீரை ஆவிபோகாதபடி 3 ¾ நாழிகைக்குள் அதன் நிறக்குறியையும் அதில் எண்ணெய்விட்டுப் பார்த்து காணப்படுகின்ற குறியையும் கவனித்து பிணிகளின் தீரும், தீராக் குறிகளை அறியலாம்.

**சிறுநீரின் பொதுக்குணம்**

"வந்த நீர்க்கரிஎடை மணம் நுரைஎஞ்சலென்
றைந்தியலுளவவை யறைகுது முறையே"

- நோய்நாடல் நோய்முதல்நாடல் பகுதி – I

**நெய்க்குறி**

நீர்நிறக் குறியால் நோயைக் கண்டு பிடித்தற் பொருட்டுச் சொல்லியிருக்கின்ற விதி பொருந்திய சிறுநீரில் ஒரு சிறியதுளி எண்ணெய் நடுவில் கையசைவினால் எண்ணெய்துளி சிதறாமல் விட்டு வெய்யிலானது அந்நீரில் படும்படி திறந்து காற்றானது அதில் வீசி அந்த எண்ணெய்த துளி ஆடாதபடி வைத்து அச்சிறுநீரில் விடப்பட்டிருக்கின்ற எண்ணெய்த் துளியானது செல்லுகின்ற வழியில் கண்ணறிவையும், உயிரறிவையும் செலுத்தி, அத்துளி தெரிவிக்கும் நோய் விளக்கத்தை தெரிந்து கொள்ளலாம்.

"அரவென நீண்டின.்.தே வாதம்
ஆழி போற்பரவின் அ.்.தே பித்தம்
முத்தொத்து நிற்கின் மொழிவதென் கபமே"

- நோய்நாடல் நோய் முதல்நாடல்

In Kumbavatham patients during neikuri examination the oil spreads like snake and sometimes like ring and pearl.

**UYIR THATHUKKAL**

**VATHAM**

***Pranan:***

Physiological function: Inspiration and expiration responsible for sneezing coughing and belching

Features in Kumba vatham: Not affected

***Abanan:***

Physiological function: Act with downward movement

Features in Kumba vatham: Not affected

***Viyanan:***

Physiological function: Helps in various movements of body, responsible for sensation

Features in Kumba vatham: Affected pain and Restricted movement of shoulder joint.

***Udhanan:***

Physiological function: Regulates the higher functions of brain. Responsible for physiological reactions like hiccough and vomiting

Features in Kumba vatham: Not affected

***Samanan:***

Physiological function: Regulates all other vayus

Features in Kumba vatham: Affected

***Nagan:***

Physiological function: Responsible for intelligence helps in opening and closing of eyes

Features in Kumba vatham: Not affected.

***Koorman:***

Physiological function: Responsible for lacrimation. Helps to visualization of all things in the world.

Features in Kumba vatham: Not affected.

***Kirugaran:***

Physiological function: Drippling of saliva, Rhinorrhoea.

Features in Kumba vatham: Not affected.

***Thevathathan:***

Physiological function: Responsible for laziness. Rotation of eyeballs

Features in Kumba vatham: Affected (Sleeplessness present due to pain).

***Thananjeyan:***

Physiological function: Responsible for tinnitus oedema.

Features in Kumba vatham: Not affected

**PITHAM**

***Anar pitham:***

Physiological function: Digests all the ingested particles.

Features in Kumba vatham: Not Affected

***Ranjaga pitham:***

Physiological function: Increases the blood and gives blood colour

Features in Kumba vatham: Not Affected

***Saathaga pitham:***

Physiological function: Makes the work to complete what mind thinks to do

Features in Kumba vatham: Affected shoulder pain and restricted movement of shoulder.

***Aalosaga pitham:***

Physiological function: Responsible for clear vision.

Features in Kumba vatham: Not Affected.

***Prasaga pitham:***

Physiological function: Gives colours to skin

Features in Kumba vatham: Not affected

**KABAM**

***Avalambagam:***

Physiological function: Controls other 4 types of kabam

Features in Kumba vatham: Affected (santhigam affected)

***Klethagam:***

Physiological function: Moistens the food

Features in Kumba vatham: Not affected

***Pothagam:***

Physiological function: Helps to know the taste

Features in Kumba vatham: Not affected

***Tharpagam:***

Physiological function: Gives cooling effect to the eyes

Features in Kumba vatham: Affected burning sensation of eye present

***Santhigam:***

Physiological function: Gives lubrication to joints

Features in Kumba vatham: Affected (pain in shoulder joint)

**SEVEN PHYSICAL CONSTITUENTS OF BODY**

***Saaram:***

Physiological function: Strengthens the body and mind

Features in Kumba vatham: Affected

***Senneer:***

Physiological function: Preserves brightness, boldness, power& knowledge

Features in Kumba vatham: Affected

***Oon:***

Physiological function: Gives structure and shape to the body.

Features in Kumba vatham: Early stage - Not affected

Later stage - Affected

***Kozhuppu:***

Physiological function: Responsible for movement lubricants the joint

Features in Kumba vatham: Affected

***Enbu:***

Physiological function: Responsible to joint movements

Features in Kumba vatham: Affected

***Moolai***

Physiological function: Present inside the bones and gives strength to the bones

Features in Kumba vatham: Not affected

***Sukkilamor suronitham:***

Physiological function:

Features in Kumba vatham: Not affected

**GNANTHRIYAM**

***Mei:***

Physiological function: Feels the sensation of touch

Features in Kumba vatham: Not affected

***Naa:***

Physiological function: Analyses taste

Features in Kumba vatham: Not affected

***Kan:***

Physiological function: For vision

Features in Kumba vatham: Not affected

***Mooku:***

Physiological function: For smell

Features in Kumba vatham: Not affected

***Sevi :***

Physiological function: For hearing

Features in Kumba vatham: Not affected

**Kanmenthiriyam**

***Kai***

Physiological function: - Handling the things

Features in Kumba vatham: Affected shoulder joint pain numbness, Restricted movement of shoulder joint

***Kal***

Physiological function: - Walking

Features in Kumba vatham: Not affected

***Vaai***

Physiological function: For speaking

Features in Kumba vatham: Not affected

***Eruvaai***

Physiological function: For defaecation

Features in Kumba vatham: Not affected

***Karuvaai***

Physiological function: For reproduction

Features in Kumba vatham: Not affected

**THINAIGAL**

***Kurinji***

Place: Mountain and its surroundings

Common diseases: Kabanoi, liver disease are common

***Mullai***

Place: Forest and its surroundings

Common diseases: Pitha and vatha disease liver disease and common

***Marutham***

Place: Field and its surroundings

Common diseases: Safest place to maintain good health

***Neithal***

Place: Sea and its surroundings

Common diseases: Vatha disease and liver enlargement are common

***Paalai***

Place: Desert and its surroundings

Common diseases: Vatha pitha and kabha disease and common

Most of the patients came from Marutha nilam. Patients were also reported from neithal nilam.

**PARUVA KAALANGAL**

***Kaarkaalam***

Aavani and Purattasi(August 16 – October 15)

Kuttram- Vatham ↑ ↑Pitham ↑

***Koothirkaalam***

Ayppasi and karthigai(October16 – December15)

Kuttram - Vatham (-)Pitham ↑ ↑

***Munpanikaalam***

Maargali and Thai(December 16 – February 15)

Kuttram- Pitham (-)

***Pinpanikaalam***

Maasi and Panguni(February 16 – April 15)

Kuttram- Kabam ↑

***Elavenilkaalam***

Aani and Aadi(April 16 – June 15)

Kuttram- Kabam ↑↑

***Muduvenilkaalam***

Aani and Aadi(June 16 - August 15)

Kuttram- Vatham ↑Kabam (-)

**Differential diagnosis**

**சகனவாதம்**

"கேளுமே கழுத்தின் கீழரைக்கு மேலுங்
கெபியான கரமிரண்டு மிகவே நொந்து
வாளுமே சரீரமெல்லாம் கனத்திருக்கும்
வாலிபர்க்கு மனங்கண்ணு மயக்கமாகும்
ஏளுமே யிரண்டு கண்ணு மெரிச்சலுண்டா
மேற்றமாய் சலந்தானு மிறுகிக்காணுந்
தேளுமே கொட்டினது போற்கடுக்கும்
சகனவா தத்தினிடே தீர்க்கந்தானே"

- யூகி சிந்தாமணி 800

இந்நோய் கழுத்தின் கீழிருந்து அரையின் மேல்வரையும் உள்ள இடமும் கைகால்களும் மிகநோதல், உடல்முற்றுங் கனத்துக் காணல், மயக்கமுண்டாதல், சிறுநீர்கட்டல், உடல்முழுமையும் தேள் கொட்டியது போன்று கடுத்து நோதல் ஆகிய குறிகளை பெறும்.

**2. பாணிக்கம்ப வாதம்**

"மார்க்கமாய் வாய்வுமாய் மெய்நிறைந்து
வயிறுதனிற் பசியிலா தூணுமற்று
நார்க்கமாய் ஞாலத்து நடக்கையற்று
நடுக்கமாய் கையிரண்டுந் திருமிருண்டாம்
ஊர்க்கமா யுறக்கமில்லா துணர்ச்சி யற்று
உதறியே சரீர மெங்கு முலர்ந்து காணுந்
பார்க்கமாய் வாய்விட்டு அலர்த்தலாகும்
பாணிக்கம்ப வாதத்தின் பாங்குதானே"

- யூகி வைத்தியசிந்தாமணி

இந்நோய் உடல் முற்றிலும் வளிக்குற்றத்தை நிறைத்துப் பசித்தீயைக் கெடுத்து நடக்க முடியாமை, கைகால் நடுக்கம், கைதிமிர்தல் தூக்கமின்மை, உணர்ச்சியின்மை, உடல் வற்றிப்போதல், வாய்பிதற்றல் ஆகிய குறிகளையும் காட்டிக் காலை மடக்க முடியாமற் கொம்பை போல் நிலைக்கச் செய்துவிடும்.

**Line of Treatment**

According to siddha system of medicine, any disease management has three stages.

- Kaapu (or) Prevention
- Neekam (or) Treatment
- Niraivu (or) REstoration

**Kaapu or prevention**

- Avoid excessive weight lifting
- Maintain proper posture while sitting
- Sleep without pillows
- Avoid watching television for a long period.
- Avoid excessive cold exposure.

**Neekam (or) Treatment**

The main aim of treatment in siddha system in equilizing the lost equilibrium in three humour . Hence the below order in followed in the treatment of Kumba vatham.

- Purgatives
- Internal and external medicines
- Diet and advises
- Kanma neekam

**1. Purgatives**

The purgatives are given to correct the deranged vatham.

"விரேசனத்தால் வாதம் தாழும்".

**Mostly used purgatives are**

- Vellai ennai – 10-15ml
- Agathiyar kuzhambu – 50-100mg
- Merugulli thylam – 10-15ml
- Vadhanaasa thylam – 10-15 ml

**2. Internal and External Medicines**

There are numerous medicine which have anti-vadha property. Some of them are

**Internal**

1. Nilavembu kudineer
2. Parangipattai kudineer
3. Amukura choornam
4. Thirikadugu choornam
5. Silasathu parpam
6. Muthu parpam
7. Naga parpam
8. Sandamarutha chenduram
9. Arumuga chendhuram

**External**

1. Sivappu kukil thylam
2. Vidamutti thylam
3. Arka sheerathi thylam

4. Vadha kesari thylam
5. Chittramutti thylam

**2. Diet and advises**

Pathiyam (or) dietary regulation should be strictly followed while eating internal medicines is not followed it may antasonize drug effect and can produce unwanted results.

"பத்தியத்தாலே பலனுண்டாகும் மருந்து
பத்தியங்கள் போனால் பலன் போகும் - பத்தியத்தில்
பத்தியமே வெற்றிதரும் பண்டிதருக் காதலினாற்
பத்தியமே வத்தியென்று பார்"

- தேரையர் வெண்பா

**4. Kanma Neekam**

To expiate the effects of kanmam, following measures are advised.

- Planting yound trees
- Laying roads
- Digging wells
- Establishing garden's
- Constructions temples
- Charity

**Niraivu or restoration**

Any residual effects of the disease should be cleared and the patient shouyld return to his normal life. To restore the activities of the life, special therapy of much essential.

**SIRAPPU MARUTHUVAM FOR KUMBA VATHAM**

**1.THOKKANAM**

**2. OTTRADAM**

**THOKKANAM**

Thokkanam is the siddha way of touch therapy. it is the physical manipulation of the body usually done with or without oil application. It is very effective for neurological and musculoskeletal problems. It also promotes mental and physical fitness. According to siddha, disease in the body occur due imbalance of three humours that is vatham, pitham and kapham which in turn are governed by five fundamental elements – Akayam (Space, vayu (air), Theyu (fire), Appu (water and Mann (Earth. Thokkanam is one of the 32 types of external medicines mentioned in siddha literature. In this technique, the physician uses his hands on the body of the patient in 9 different unique ways with or without using medicated oil with acurative or palliative point of view. The 9 different techniques in thokkanam which makes siddha medicine unique in all aspects. They are

1. Thattal or patting technique
2. Irukkal or tightening
3. Pidithal or holding
4. Murukkal or twisting
5. Kattal or tying
6. Azhuthal or pressing
7. Izhuthal or pulling
8. Mallathuthal or supinating

**Benefits of Thokkanam**

- Helps to cure vatha disease even without internal medicines.
- Chronic disease like spondylosis, lumbago, disc prolapse, hemiplegia, neurological conditions etc are managed well through thokkanam.
- Improve circulation
- Treats obesity
- Helps in pain relief
- Removes indigestion, constipation and flatulence
- Induce sleep

- Helps maintain normal blood pressure
- Restores vatham, pitham and kapham in normal ratio
- Regulates vatha humour.
- Delays the aging process
- Helps to rejuvenate the body.
- Helps to increase the quantity of oxygen in the cells.
- Helps to prevent wrinkles and maintain the complexion of the skin.
- Tones the muscles
- Helps to keep the joint flexible
- Improves the complexion of the skin
- Improves energy and mental alertness.

**Introduction**

External remedies in siddh are classified as 32 in number. The unique remedy of its kind among all and which is subdivided into nine more procedures in thokkanam. Initially these procedures were used only for royal families to enhance rejuvenation and latter turned into a therapeutic application.

Thokkanam as a whole focuses on treating disease caused by aggravation of 'VATHAM' the kinetic force of the body. The humoral theory of siddha states that vatham is the acitve force responsible for the physiological functioning of neuromuscular as well as musculo skeletal systems.

Thokkanam is also useful in disease where pitham as well as kapham is deranged. A simple thokkanam session wipes of sedentary feel which is a kapham aggravation.

Thokkanam is a word framed by combining two words, Thokku and Anam. Thokku means SKIN. Anam mean support/tones/heat.

Toning the skin, muscles and nerves where vatham lives. It is synonymously called as Marthanam. Marthanam is performed by mallars (wrestlers) in older days. Mallars are musculine with calibre to perform martial arts including wrestling.

As per siddha basic principles the meeting points of muscles, nerves, joints and skin including hair roots are places of flow of vital vatham energy. A depletion of vatham vital energy may lead to vatham derangements such as pain, altered tone, power, twitching, spasticity, rigidity numbness and neuritis.

**Three humour theory and thokkanam**

To have a sound knowledge in application of thokkanam clinically it is mandatory to know about three humour theory. Vatham is the force of creation. Pitta is the force of maintenance, and kapham is the force of destruction.

Vatham takes care of bodily funciton as below

1. Respiration - Uyirkal (Pranan)
2. Excretion - Keel nokku kaal (Abanan)
3. Circulation - Paravukal (Vyanan)
4. Digestion - Nadukkal (Samanan)

**Thattal – Friction and Percussive strokes**

Friction and perucssive strokes are most used techniques in Thokkanam. Thattal covers more than 40% of techniques of Marthanam.

Friction strokes are used in joints, muscles and in tendons. Friction strokes are usually relaxing when applied gently. Therapist should not exceed the toleratble and pleasurable pressure.

Percussive strokes are sub divided into hacking, cupping and pinching – plucking. Hacking is like chopping in a slaughter house. In hacking palms are open and faces each other.

Cupping is performed effectively in larger areas like trunk, back and abdomen.

Lifting little flesh in fingers and sliding them is pinching/plugging.

**Benefits**

1. Improves circulation
2. Release muscle tension.

**Precautions**

Precussive strokes directly on spine is to be avoided. Therapist hands and wrist should be held relax.

**Irukkal**

Irukkal is squeezing type of pressure. Irukkal is applied in conditions where a good nourishment to muscles and nerves is deficit. It is also called as wringling. It is usually performed across body and limbs. Wringing is usually applied in the end hours of Thokkanam. Squeeze and roll the muscle between your neck and shoulder. It's hard to tell from the photo that he's doing anything other than squeezing the

muscle, But you should in addition to squeezing your muscle also pull or roll the muscle between your fingers. Try it. first squeeze the muscle, just like you did above. Then pull it a little and roll it in a small circle of back and forth. Try 7 slow squeeze and rolls on your trapezius muscle varying the intensity of each stroke. Let your muscles relax.

**Purpose**

Squeezing and Rolling increases your circulation and warms your muscles. It also gives your fingers a good workout.

**Stroke description**

This is a two step stroke. First squeeze the muscle. Then pull the muscle and roll it between your fingers. the rolling motion moves the muscle up and down. It pulls the muscle away from your body. It's similar to kneading dough.

**Ilutthal**

Ilutthal is pulling. In this type of thokkanam, strokes are used to pull and stretch the muscles of the trunk and legs. Pulling is performed before wringing or along.

**Murukkal**

Murukkal is kneading. It is performed to release muscle tension and to improve circulation kneading is performed in areas which are fleshy. Action similar to that of kneading dough is to be performed here.

**Pidithal**

Both pressing and draming is performed in this variety. Press the muscle areas gently and drain them slowly. Draining is performed usually using the heel of the hand for larger areas and thumbs for smaller areas. Pidithal improves circulation and relaxes the muscles.

**Aluthal**

Aluthal is the combination of gliding and gentle pressing. Usually these two procedures initiates massage and repeatedly performed in the whole session gliding is the technique used to apply oil all over the body. Gentle pressing all over the body following gliding. Gliding can be done in longitudinal or circular motion.

**Purpose**

Gliding is a good beginning for every massage. It warms your skin and sends a message to your body that a massage is coming.

**Stroke Description**

Glide your hand overy your skin.

**Note**

Massage therapists call this stroke by its french name effleurage which means gliding or skimming.

**Tips**

Velocity, volume and intensity are three variables you can use to change the effect each stroke has on you.

**Volume**

Try covering more skin with each stroke by spreading your fingers wide or make a with your hand

**Velocity**

Try varying the speed of your strokes

**Intensity**

Try varying the intensity of each stroke

**Squeezing**

Try it interlace your fingers. Rest the heels of your hands on either side of your thigh and squeeze your hands into your thigh muscles. Try 7 slow quad squeezes, slightly vary the location and intensity of each squeeze. Now try it on your other leg.

**Purpose**

Squeezing warms muscles, increases circulation and speeds recovery.

**Stroke description**

Bring pressure to bear on a muscle. Try squeezing your left biceps with your right hands. It really is a simple as squeezing the muscle. It should feel good.

**Squeezing & Rolling**

Try it: Squeeze and roll the muscle between your neck and shoulder. It's hard to tell from the photo that he's doing anything other than squeezing the muscle. But you should in addition to the muscle. Just like you did above. Then pull it a little and roll it in a small circle of back and forth. Try 7 slow squeeze and Rolls on your trapezius muscle varying the intensity of each. Stroke let your muscles relax.

**Purpose**

Squeezing and Rolling increases your circulation and warms your muscles. It also gives your fingers a good workout.

**Stroke description**

This is a two steopstroke, first squeeze the muscle just like you did above. Then pull the muscle and roll it between your fingers. The rolling motion moves the muscle up and down-it pulls the muscle away from your body. It's similar to kneading dough.

**Pressing**

Try it. Take off your shoes and socks and give your foot a poke, press your thumb into the bottom of your foot and your other four fingers into the top of your foot. Try 7 slow presses. Experiment by varying intensity and moving your fingers slowly over your foot. Try it on your other foot.

**Purpose**

The press is powerful because it activates acupoints triggers trigger points, jump starts circulation, and sends endorphin cocktails flowing to every cell.

**Stroke description**

Press or poke a muscle into the bone, using one or more fingers, elbows. Hold the press from 1 to 30 seconds.

Note: Massage therapists call this stroke compression

**Pressing and Rolling**

Try it: Starting at your solarplexus. Press and roll your abs. Perform a series of small circular rolls with your first moving clockwise, until. You've covered your entire belly with your first slightly vary the intensity of each stroke. Alternately, relax

and flex your abs. Feel the difference between pressing and pressing and rolling your abs. It's like night and day.

**Purpose**

Pressing and Rolling activates, acupoints triggers trigger points, jump starts circulation and sends endorphin cocktails cruising to stimulate every cell in your body.

**Stroke description**

The press and roll in the press with a twist. Press the muscles into the bone to compress them. Then roll or rotate your press. The fingers, elbows or fists can be used to press and roll the muscles.

Note: This stroke can be used for deep tissue massage.

**Drumming**

Try it: Drum your quads, use the sides of your hands to tap your thighs. Slightly vary the location of each stroke. Let your leg relax. focus on the rhythm and feeling of each stroke.

**Purpose**

Drumming is an energizing, stimulating stroke, used to get you moving.

**Stroke description**

Lightly drum or tap your hand on your body. By varying the part of your hand drumming your body. The feeling of the stroke changes some examples are open flat hand open cupped hand site of hand, first, knuckles, side of fist and fingertips.

**Note**

Massage therapists call this stroke trapotement It means drumming.

When you need to target a specific area of your body, switch over to manual mode. Customize your massage and choose from several programs to suit your needs for both upper and lower body. The upper body massages.

The thadavu murai is classified into two main parts. They are

1. Podhu thadaval murai
2. Uzhl thadaval murai

The pothu thadaval murai methods do proper alignment of the nerves, blood vessels, bones and muscles. With the help of medicated oils we should do the techniques. After that we have to realign the sara ottam and jeeva ottam in all varma points. By this we can give good health to the patient.

After doing this, we should check whether the patient needs uzhlthadaval murai or not. It it is needed we have to align and stimulate the tissues and internal organs.

In the first three days of treatment we should only do podhu thadaval methods, then in the $4^{th}$ and $5^{th}$ day podhu thadaval is done followed by uzhlthadaval.

Usually the treatment takes seven days. In the $6^{th}$ and $7^{th}$ day. We should only do podhu thadaval.

At the end of the thadaval murai in all the days of the treatment.

We have to give otradam, after that the patient should take hot water bath. After that the patient should take chukku kanji. The patient may take their food after an hour of these treatment methods. During the treatment days the patient must avoid sleep in the day time.

According to the patients health condition we have to give medicines such as karungozhi decoction. Karungozhi nei or vellattu nei.

The patient should follow the following food restrictions after the thadaval murai. Chicken, uriddhal, small gram and tamarind during the treatment days. Because it may lower the effects of the treatment.

The patient should take 3 months rest after the treatment. Importantly he/she should not have sexual contact and severe exercises during the rest periods.

**Massage (தொக்கணம்)**

வாதம் முதலிய முக்குற்ற பிணிகள் உண்டாக்கும் வலியை வெறுங்கையாலோ (அ) தைலம் தடவியோ பிடிப்பது.

தொக்கணத்தி னாலிரத்தந் தோல்ஊ ணிவைகட்கு
மிக்கு சவுக்கியஞ்ச மீரணும்பொ – மெய்க்கதிக
புட்டியுறக்கம் புணர்ச்சி யிவை கதிக்கும்
பட்ட அலைச்சலறும் பார்"

- **தேரன்**

of these 2 of the methods are very much beneficial in treating cervical spondylosis.

**பிடித்தல்**

"பிடித்தலி யங்கும் மைதியி னுந்தகும் பிந்தாதே – எண்ணெ
யுடுத்தது செய்யிற் றசவளி யூனுட லுந்தாதே
வேற்றது செய்யினுஞ் சூசிகை பாரிசை விட்டோடும் - புலி
போற்றது வாயுவு மற்றுது மேனலிப் பொட்டோடும்"

தொக்கணம் செய்யக்கூடிய 5 நிலைகளிலும் செய்யலாம். தைலம் தடவியோ, தடவாமலோ பிடித்துவிட வாத நோய்களுக்கு சிறப்பாக பொருந்தும்.

It is made on the upper fibers of trapezius muscle and the underlying bone.

**இழுத்தல் (Pulling)**

இழுத்தல் கிடத்த லிருத்த லிரண்டிற்கு மேராமே – என்பில்
முழுத்தது வண்ணுகங் கானமந் தக்கதி சீராமே
உருவுத லென்பது மித்தோழி லேநேரம் பூறாகி – மனம்
வெருவுறு மூன வினைகளை மெய்யடு வேறாகி
வளக்குறு மெண்ணெய் லேயிது செய்வது வல்லாண்மை – உடற்
களக்களுர் போக்கச் சுளுக்கென வாவதித் தொல்லாண்மை"

இதை தைலத்தை பூசியே செய்யவேண்டும். எலும்புகள் நன்றாய்த் தெரியுமிடங்களிலும், தலையிலும் உருவும்போது மந்தமாக செய்யவேண்டும்.

இதனால் நரம்பில் ஊறி வறுத்துகின்ற வாயுக்கள், பிடிப்புகள், சுளுக்குகள் குணமாகும்.

Done for sternocleidomastoid muscles.

The treatment normally starts with applying the medicated oil on the affected area. It directly acts on lymphatic, muscular, nervous and vascular system.

- Strengthens muscle and skin
- Relaxes whole body
- Regulates nerve function

- Improve blood circulation
- Improve sleep

Through massage, the medicated oil applied permeates through the skin and reaches the tissues under them. It releives pain and tension by stimulation the sensory and motor nerves.

**Benefits**

It reduces the production of some hormones such as cortisol and nor epinephrine which are responsible for stress.

- Brings fresh oxygen to the affected tissues.
- Swelling and thickening of tissues are reduced.

**FOEMENTATION**

**Definition**

A fomentation consists of a local application of moist heat to the body surface. A fomentation is usually made of blanket material. 50% wool to retain heat and 50% cotton to retain moisture and be more durable.

**Physiologic effect**

1. Promotes increase in circulating white blood cells.
2. Increases blood flow to the skin, thereby relieving internal congestion.
3. Relieves muscle spasm by increasing circulation and releasing muscle tension.
4. Relieves pain in muscles and joints by counter-irritation and de congestion.
5. Reflexly relieves pain from internal organs.
6. Increases elimination by promoting sweating
7. Stimulates or sedates according to the temperature of the application.

**Indications**

1. Joint pain
2. Neuralgia and Neuritis pain
3. Muscle tension
4. Insomnia
5. To warm the tissues in preparation for massage.
6. To prepare for cold procedures.

**Contra indications and cautions**

1. Loss of skin sensation due to unconsciousness paralysis of the part legs and feet of diabetic
2. Leg or feet oedema, varicose veins, advanced vascular disease.
3. Malignancy
4. Tendency to bleed (haemorrhage)
5. Stomach or bowel ulcers.
6. Omit cold in extreme pain such as pleurisy, Renal colic and dysmenorrhoea.

**ஒற்றடம் (Fomentation)**

மருந்து பொருட்களை வறுத்து துணியில் முடிந்து நோயுள்ள இடங்களில் ஒற்றுதல்.

It is also one of the 32 external theraphies of siddha medicine by application of hot medicated packs.

The medicated pouches are made up of leaves that contains.

- Pelonex elata (வாத நாராயணன் இலை)
- Tamarindus indicus (புளியிலை)
- Vitex negundo (நொச்சி)
- Cleodendrum phlomoidis (தழுதாழை)

**Uses**

Increases blood circulation and reduces pain.

# MODERN ASPECT

## SHOULDER JOINT

**Classification:**

It is the synovial polyaxial and the ball and socket joint.

**Bone taking part:**

Glenoid cavity of the scapula and the head of the humerus.

**Glenoid cavity:**

It is pear shaped, shallow articular cavity situated at the lateral angle of the scapula. It is covered with the hyaline cartilage. A flattened impression is pressure at its periphery for attachment of fibrocartilaginous structure known as glenoid labrum.immediately below the cavity less a small rough tubercle. It is known as intraglenoid tubercle a similar tubercle lies above the cavity and it known as supraglenoid cavity. It is significant to note that the glenoid cavity is directly forward and laterally.

The movement of flexion and extension take place along this plane and bringing the flexed arm in front of the chest the size of the head of the humerus is grossly disproportionate to the size of the glenoid cavity which is smaller, which contributes the free mobility of the joint.

**Head of humerus:**

The head is hemispherical and is covered with hyaline cartilage. The layer of hyaline cartilage is thick in the centre of the head and thin at the periphery. Reverse is the case with the glenoid cavity.

Head of the humerus is protected above by coracoacromion arch which is formed by the coracoids process, coraco acromial ligament and the acromion process. The coracoacromial arch is considered as the secondary socket for the head of the humerus. This prevents upward displacement of the head of humerus which impinges against the coraco acromial arch.

**Attachment of the capsule:**

Proximally the capsule is attached to the rim of glenoid cavity beyond the glenoid labrum. Superiorly it includes the supraglenoid tubercle. Which gives origin to the long head of biceps and hence the long head of biceps is intracapsular but extra

synovial epiphyseal line of the upper end of humerus lies with in the capsule. This results is involvement of the joint in case of osteomyelities of the upper end of humerus.

Distally the capsule is attached to the anatomically neck of the humerus, immediately beyond the articular area of the head. However, capsular attachment decents 1 to 1.2cm below on the medial aspect of the shaft. It is interrupted at the upper end of the bicipital groove the long head of the biceps along with its synovial sheath. As a result decent of the capsular attachment of the joints on the medial side of the neck of humerus it become loose and weak. This allows abduction of the shoulder without much tension on the interior part of the capsule. However it helps osteomyelitis of the upper end of humerus to reach the shoulder joint

**Ligaments of the shoulder:**

- Capsular ligament
- Glenohumoral ligament
- Coracohumoral ligament
- Transverse ligament
- Glenoidal ligament

Glenohumoral ligament is divided into three separate bands (ex. Superior, middle, and the inferior gleno humoral ligament)

Members of the rotator cuf (ex. Subscapularis, supraspinatus, infraspinatus and the teres minor form the musculotendinous cuff along with the capsule of the shoulder joint. It is known as rotator cuff)

There are three openings in the capsule they are

1. Opening for communication with suprascapular bursa. It lies between the superior and middle glenohumoral ligaments.
2. Opening for the long head of biceps with its synovial membrane
3. The third one is inconstant and when presents its communication with the bursa of the infraspinatus muscle.

Opening between the superior and the middle glenohumoral ligaments is meant for the subscabular bursa. It provides the weak spot for escape of the head of humerus during dislocation. Subscapular bursa of a size of a hens egg and is placed between between the neck of the scapula and the subscapularis muscles.

**Gelenohumoral ligaments:**

Cavity and the humerus they are three in numbers namely the superior, middle and the inferior. All the three can very well be examined from inside the capsule. Medially they are attached to the medial margin of glenoid cavity. Its upper part here they practically fused with the glenoid labrum. Laterally the superior and the middle ligaments gain their attachment on the lesser tubercle.

The inferior glenohumoral ligament is attached to the lower part of the anatomical neck of the humerus. The part of the capsule near the attachment of the superior band of the inferior glenohumoral ligaments. It known as axillary power in interior dislocation of the shoulder joints the inferior glenohumoral ligament is form along with the damage to the superior band of the inferior glenohumoral ligament and the part of the glenoidal labrum helps recurrent dislocation of the shoulder. However recently absence or advancement of middle glenohumoral ligament extending on the scapular neck is consider as an important feature in recurrent dislocation of the shoulder.

**Coracohumeral ligaments:**

It is increases the strength of the upper part of the capsule it runs from the root of coracoid process to the anterior part of the greater tubercle of the humerus during, it is course practically fuses with the supraspinatus tendon.

**Transverse humoral ligament:**

It bridges the gap between the two tubercles of humerus converting the upper part of the bicipital groove in to the canal. Its attachment lies above epiphyseal line functionally it acts as a retinaculam for retention of the tendon of the long head of biceps.

**Glenoid labrum:**

It is a fibrocartilaginous ring situated along the margin of glenoid cavity. It presents of a base, which is fixed to the flattened impression at the periphery of the glenoid cavity and the sharp free edge, it lying free, for the contact with the humeral head. Superiorly two fascicule of the tendon of long head of biceps fuse with the anterior and the posterior parts of the glenoidal labrum are

1. Deepens the cavity
2. Maintaining the bony contact and protects the edges of the glenoid cavity.

**Synovial membrane:**

The synovial membrane of the joints covers the capsule from inside and other structure except articular areas there is a separate tubular sheath of synovial membrane for the long head of biceps the synovial membrane of subscabular bursa is continuous with synovial membrane of the joints through the opening for subscabular bursa.

**Bursae around the joints.**

- Subscapular bursa
- Infraspinatus bursa
- Subacromial bursa
- Supra acromial bursa
- Subcoracoid bursa
- Bursa between coracobrachialis and the capsule.
- Bursa between teres major and long head of biceps
- Bursa in front and behind the tendon of latissimus dorsi.
- Subscabular bursa is the only bursa which communicate with the joint cavity.

**Subacromial bursa:**

It is situated between the supra spinatus tendon below and the coraco acromial arch above. This is the longest of the bursa in the body. When it extents below the deltoid muscle it is known as subacromial, subdeltoid bursa. In subacromial bursitis patiently experiences pain when pressed below the acromian. After abduction of the arm the pain disappears and the tenderness is missing.

**Supra-acromial bursa:**

It is placed above the acromian while the corocoid bursa lies below the corocoid process.

**Relation of the joints:**

Following are the relation of the joints.

**Superior relations:**

- Deltoid
- Coracoacromial arch
- Subdeltoid subacromial bursa
- Tendon of supraspinatus

**Posterior relations:**

- Deltoid
- Subscapularis
- Subscabular bursa
- Coracobrachialis
- Short head of biceps
- Clavicular head of pectoralis major

**Posterior relation:**

- Deltoid
- Infraspinatus
- Teres minor

**Inferior relations:**

They are important as the axillary nerve along with the posterior circumflex humoral artery and long head of the triceps lie below the joints. Apart from these relation axillary artery must be mentioned as the rupture of the artery is likely to occur, during dislocation of the shoulder and reduction of an old dislocation.

**Nerve supply:**

- Axillary
- Suprascapular
- Lateral pectoral nerve
- Lateral pectoral nerve supplies pectoralis major
- Suprascapular nerve supplies supraspinatus and infraspinatus muscle
- Axillary nerve supplies deltoid and te teres minor

**Blood supply:**

Three arteries supply in the joint

- Anterior circumflex artery
- Posterior circumflex artery
- Suprascapular artery

**Biomechanics of the shoulder:**

**Kinematics:**

Abduction is a very importent movement at the shoulder. It is well known that bpoth abduction in the coronal plane from 0 to 180 degree and forward flexon in the sagital plane from 0 to 180 will plane the upper limb in the same position with the medial epicondyle pointing medially and forwards. This is because of the fact that in abduction in the coronal plane, the humerus relates externally to prevent impigment of the greater tuberosity on the coraco acromial arch. The greater tuberosity rotates posteriorly to allow full abduction. Persons with internal rotation contracture of abduction due to this reason. The plane of the scapula is 30 degree anterior to the coronal plane of the shoulder and in this plane no rotation of the humerus is required for full abduction of the shoulder.

The full range of abduction involves 120 degree of glenohumoral and 60 degree of scapulothoracic motion. The scapula thoracic rhythm is the rotation of the glenohumoral to the scabulothoracic movement.the rotation is depend on the plane of abduction for aduction in the true coronal plane the ratio of glenohumoral to scapulothoracic movement is 2:1 and for abduction in the scapular plane, the ratio is 1:35:1 scapulothoracic movement in the sum of movement at the acromioclavicular and sternoclavicular joints. The clavicle abduction 4degree for each 10 degree of abduction beyond 90 degree of abduction, further movement of the clavicle is negligible. The acromioclavicular joints moves about 20 degree during abduction of the shoulder. This movement occurs during the first 30 degree and beyond 135 degree of abduction between 30 and 135 of abduction. The movement at the acromioclavicular joint is negligible movement at the sternoclavicular and an acromioclavicular joint is made possible due to rotation of the clavicle. The clavicle rotates by about 50 degree during abduction and is this rotation is prevented. Shoulder

abduction is limited to 110 degree the curvature of the clavicle acts as a crankshaft allows in elongation of the coracoclavicular ligament.

**The force couple:**

The deltoid and supraspinatus are the main abductors of the shoulder. The infraspinatus, Subscapularis and teres minor tend to depress the humeral head during abduction. Since the glenoid fossa is shallow, the action of the deltoid alone would displace the humeral head out of the socket with the arm by the side, the deltoid tends to pull the humerus up and sublux the humerus head superiorly the rotator cuff muscle prevent this subluxation by pressing the humeral head into the glenoid. The deltoid and the rotator cuff are part of the force couple acting on the humeral head. The force couple consists of two opposing forces acting on an object and separated from each other by some distance, so that they rotate the concerned object. The multipennate nature of the deltoid adds power to its contractions. In a multipennate muscle the overall change in length required for a given contraction force is less than that for a muscle with parallel arrangement of fibres such as the biceps. Also as the scapula rotates during abduction the distance between the acromion and the deltoid insertion increases and this maintains the length of the deltoid near to us resting length.

In the scapula, the upper portion of the trapezius, levator scapulae and upper portion of serratus anterior form a force couple with the lower trapezious and lower portion of the serratus anterior causing rotation of the scapula during abduction of the shoulder.

Adduction of the shoulder is carried out by pectoralis major, teres major and latissimus dorsi forward  flexon is done by pectoralis major, anterior fibres of the deltoid and biceps. Extension is carried out by latisimus dorsi and posterior fibres of deltoid internal rotation is the function scapularis and teres major external rotation is done by infraspinatus, teres minor and posterior fibres of deltoid.

**Stability of the shoulder:**

Equilibrium is a state in which the body is at rest or in uniform motion under a given set of leads. Instability has been defined as an abnormal response to applied leads characteristic by motion in the motion segment beyond the normal constraints pope and panjab have shown that an object may be in stable, unstable or neutral equilibrium.

For the humeral head to be stable in all position the resultant of all the forces acting on the humeral head must pass somewhere through the glenoid arc.

If a passes outside the glenoid arc, stabilityoccurs. The glenoid is slightly concave and much smaller than the humeral head. This make the joint essentially unstable in the absence of other stabilizer glenohumoral joint stability depends on passive and active stabilizers

**Passive stabilizers are as follows:**

Bony features-retroversion of humeral head (35degree-40degree) and slight upward undination of the glenoid Negative intra-articular pressure exerts a suction effect. Synovial fluid adhesion and cohesion (due to its high tensile strength and low shear strength) Glenoid labrum-deepens the glenoid, although only slightlythe articular cartilage of the glenoid is thicker at the margins that at the centre. This also increase the concavity.

**Ligaments and capsule**

The volume of the shoulder capsule is twice that of the humeral head to permit mobility freely at the sometime, the capsule has condensations which form the glenohumoral which form the glenohumoral and coracohumeral ligaments that act to provide stability.

## PERIARTHRITIS SHOULDER (FROZEN SHOULDER)
## (Syn : Periarthritis, Adhesive capsulitis)

### INTRODUCTION:

Adhesive capsulities was first describe by nevisar in 1945. Both the entities, adhesive capsulities and frozen shoulder are generally thought to be the same.

A frozen shoulder (or) adhesive capsulitis is a glenohumoral joint with pain and stiffness that cannot be explained on the basis of joint incongruity it is the restriction to passive movement that is the hallmark of this disease.

Adhesive capsulitis occurs mainly during the fifth to seventh decade of life and affects women more frequently than men bilateral involvement occure in 10 to 40 percent cases. Once the syndrome resolves it generally does not recur on the same shoulder. Unless there are other predisposing factors like diabetes mellitus, bicipital tendinitis, rheumatoid arthritis ect.

Frozen shoulder is a very common disability causing shoulder pain and stiffness. its pathogenesis is not fully understood. It is the end result of many different pathological conditions. If the shoulder is immobilized for a long time due to any reason, it results into pain and stiffness.

### ETIOLOGY:

The most common causes are cervical spine degenerative disease or radiculopathy, subacromial impingement syndrome, acromio clavicular arthritis post trauma bursitis and inflammatory synovitis of the shoulder. It is also found in association with other medical problems such as diabetes mellitus and also with cardiothoracic surgery, shoulder immobilization for feature in the upper limb of adhesive capsulities. Muscle imbalance is another important cause. It also occurs due to immobilization of the upper limb after fracture. Eg. colleins fracture. There is a higher than normal association between frozen shoulder and diabetes mellitus. Depalma(1953) considered that bicipital tenosynovitis played an important part.

### PATHOLOGY:

Dense adhesions are present between the humeral head and the glenoid cavity adhesion increase as the disease progresses. The interval between the humeral head and the glenoid gets progressively narrowed. Capsular contracture is noticed. The

dependent told of the capsule gets obliterated with adhesions. The synovium is thickened reddish and eleminatous.

It has been found at surgery that a volume of the joint is reduced, and the joint capsule is tight and contracted. Appear that the coracohumoral ligament is particularly affected. Shortened coracohumoral ligament restricts external rotation and always require release during the open release.

**CLINICAL FEATURES:**

Patients complaints pain and stiffness of shoulder. often the pain is severe this condition accounts for more cases of shoulder disability than does spraspinatus tendinitis. It affects males and female equally over the age of 40 years.

In the classic descripton of adhesive capsulitis, there are three clinical phases

**1. Painfull phases:**

Initially the patient will complain about an aching discomfort about the shoulder pain gradually increases. Night pain often awakening him or her from shee is a common complaint.

**2. A phase of progressive stiffness:**

As the pain increases the movements of the shoulder get progressively restricted. This leads to stiffness of the shoulder with further restriction of movement the stiffness about the shoulder gradually increases thus a vicious cycle tends to occur. The movement most affected are external and internal rotation and abduction. There is usually no discrepancy between active and passive ranges of motion.

**3. A thawing with gradual return of motion:**

This usually occurs after 10 to 12 months or even after 3 years. The pain and stiffness reduces. Frozen shoulder is usually self-limitting, but symptoms can persists for 6 months or more, and it takes many more months for all ranges of movements to return to normal.

**Movements :**

Let the patient stand with his upper limbs hanging by the side of the chest in anatomical position i.e. shoulder adducted, elbow extended and forearm supinated. Elicit the movements (active and passive. If the active movement is restricted, possible passive range of movement can be tested by holding the patient's hand by examiner's one hand, while his 90º flexed elbow is supported by the examiner's other hand.

| S.No. | Movements | Range | Prime Muscles | Assisted by | Root Control |
|---|---|---|---|---|---|
| 1. | **Flexion**<br>Patient stands with arm hanging by the side, elbow extended and forearm supinated. Ask him to take hand towards the midline | 0°-180° | Pectoralis major, Pectoralis minor, Anterior fibres of deltoid, coraco brachialis | Biceps brachi | $C_5$ |
| 2. | **Extension**<br>Diametrically opposite to that of flexion | 0° - 45° | Latissimus dorsi | Posterior fibers of the deltoid, Teres major | $C_5$, $C_6$ |
| 3. | **Abduction**<br>Extended elbow moving away from the . The glenohumeral and scapulothoracic components of abduction can be tested as follows<br>Stand beind the patient and hold the Inferior angle of scapula in between thumb and Index finger of one hand. While doing abduction, so long as the movement is at glenohumeral joint scapula will not resist. The moment scapulo thoracic gliding starts, resistance is flet by the holding hand. Note : The extent of each component (Normal 90° +90° | 0° - 180° | Supraspinaturs, middle fibers of deltoid, seratus anterior, trapezius, latissimus dorsi. (Gliding Mechanism - Turek S.L. 1951) | - | $C_5$, Accessory nerve |
| 4. | **Adduction**<br>Diametrically opposite to abduction | 180° - 0° | Pectoralis major, Latissimus dorsi, Teres major | Gravity | $C_{5,6}$ |

| | | | | | |
|---|---|---|---|---|---|
| 5. | **External rotation**<br>While arm is by the side of the chest elbow flexed at 90° and forearm supinated move the extended hand outwards | 0° - 70° | Teres minor, infraspinatus, posterior fibers of deltoid | - | $C_5$ |
| 6. | **Internal rotation**<br>While the position as above, move the extened the hand towards the mid body plane | 0° - 80° | Subscapularis, pectoralis major, Teres major, Latissimus dorsi | Anterior fibers of deltoid | $C_{5, 6, 7, 8}$ |
| 7. | **Circumduction**<br>With the upper limb extened at the elbow and wrist, complete a circle starting from the adduction position of the arm | 360° | Combination of all the above | - | $C_5$ & $C_6$<br>Accessory nerve |

**Measurements :**

a. Linear

b. Circumferential

**Linear :**

1. Apparent measurements
2. True measurements
3. Segmental measurements should also be done.

**1. Apparent measurement :**

It is not of so much value as in the lower limbs. However, it can give some idea.

Method with the affected upper limb in a position as kept confortably by the patient the opposite upper limb is put parallel to it. Measure from the tip of the seventh cervical spine to the tip of radial styloid on both sides while the trunk is alined to the limbs.

2.True measurements prerequisities :

Limbs must be kept in identical position at each joint i.e. shoulder, elbow and wrist. Palpate and mark the angle of acromion. (pass a finger laterally on the spine of scapula, at the extreme outer end posteriorly, an angle is formed known as the angle of acromion), lateral epicondyle of the humerus and tip of the styloid process of radius.

Total linear measurement of the upper limbs is done by measuring from the angle of acromion to the tip of radial styloid process.

Segmental measurements are for arm and forearm components. For the arm, measure from acromial angle to the tip of the lateral epicondyle and for the forearm, from the lateral epicondylar tip to the tip of the radial styloid process. If the lateral epicondylar tip is not discernible (e.g. in comminuted fratures, congential absence, iatrogenic) identical fixed bony points can be taken for comparative measurement (e.g. medial epicondylar tips, radial head, oleocranon tips).

**Circumferential Measurements :**

Besides noting the wasting at the mid-arm level, or at equidistant from the acromial angles, circumferential measurements should also be done around the shoulder joint i.e. across the base of axilla to the top of the shoulder. For all practical purpose, any increase in this measurement indicates an increase in the girth of the shoulder joint and vice versa.

The anterior and posterior axillary folds should be measured and compared with the other side.

Method abduct the shoulder as far as practicable upto 90°. Keep the opposite shoulder in the same position. Axillary folds stand prominent. Measure from the junction of the axillary folds with the arm to their junction with the trunk. (Both anterior and posterior folds).

**Local examination :**

**Prerequisites :**

- Patient must be examined standing on the floor or sitting on a stool.
- Neck to the tip of fingers be exposed fully from all sides.
- Opposite shoulder must be examined for comparison.
- The limb should be kept freely hanging by the side of chest in anantomical position i.e., elbow extended and forearm supinated as far as practicable.

**Attitude :**

Attitude of the patient in relation to the shoulder is sometime typical. The position of the neck, the shoulder point, the supported or unsupported upper limb should be noted. Many a times the attitude itself is diagnostic, e.g., patient with fracture clavicle inclines his neck to the affected side and supports the elbow in opposite hand keeping the arm by the side of the chest, Patient with anterior dislocation of shoulder loses the contour of shoulder, develops flattening of deltoid bulge, drooping of axillary fold and keeps the elbow away from the chest., In luxation erecta, the arm is kept widely abducted and internally rotated, elbow extended, forearm pronated, wrist partially flexed, thumb in palm and fingers semiflexed i.e. position of the policeman receiving tip.

In Klippel - Feil syndrome (congential webbed neck), hairline lies almost on shoulder level with or without high – placed scapula. In Sprengel's shoulder - congential elevation of scapula, upper border of which may lie well above the shoulder. In deltoid contracture, there is fixed abduction deformity at the shoulder.

**Inspection :**

Inspect from the front, side, back and the top simultaneously comparing with the opposite side. Note the condition of skin, its vascularity, presence of any swelling, abnormal pulsation, wasting, fasciculation etc.,

From the front - Relation of the two clavicles from the sterno – calvicular to acromio – clavicular joint, anterior deltoid bulge, supraclavicular fossae, infraclavicular fossae pectoral bulge, anterior axillary line and folds, contour of the shoulder and approximation of the elbow to the chest.

From the sides - The deltoid bulge and the side of the arm.

From the top – Acromio - clavicular elevation and angle of acromion, the bulge of the shoulder.

From the back - Right from a mid-spinal line, medial border of scapula and scapular prominence, scapular (supra and infra-spinus) fossae, level of inferior angle of scapula, posterior deltoid bulge, posterior axillary line and folds. Any abnormality in comparison to the other side must be noted.

**Palpation :**

a. Superficial
b. Deep - locate and palpate the followings, and note any abnor mally.

**Palpate :**

- clavicle from sternoclavicular to acromiclavicular joint,
- tip of the coracoid process,
- angle of acromion,
- the body and angles of scapula,
- hollowness of the base of axilla,

- palpate the supraclavicular region for pulsation or any other abnormality of the subclavian artery and upper medial aspet of the arm for the brachial artery,
- hollowness or fullness of infraclavicular fossae,
- palpate the different groups of lymph glands in axillary and supraclavicular regions, in acute traumatic cases palpate for any dislocated articulating end or displaced bony fragment, and in late ones for any myositis or myositis mass.

**Tenderness of the shoulder joint is mainly elicited at two regions:**

Just laternal to the caracoid priocess anteriorly, and just below and behind the acromial angle posteriorly. In bicipital tendinitis, tenderness is along the biceps tendon on the antero-superior slop of the shoulder bulge. Tenderness over the region of glenoid, head of humerus, tuberosities and upper humeral shaft should be noted separately.

A cyctic swelling around the shoulder should be confirmed by the usual methods of demonstration. Collection in the shoulder joint is usually localized anteriorly, posteriorly or infero-medially. However, when the collection increases, cross-fluctuation (anteroposteriorly) can be demonstrated. A cystic hygroma, having typical compressibility and very clear trans illumination, may manifest anteriorly.

In doubtful cases of fasciculation, tapping over or squeezing the deltoid muscles can be useful in initiating the bout.

Since the muscular padding is very thick almost all around, on palpation one gets very little clue about the fracture ends unless they are quite obvious. One should not attempt to elicit crepitus and abnormal mobility. Most of the fractures around the shoulder are generally impacted and require hardly any interference. Over enthusiastic attempts at demonstrating crepitus and abnormal movements may disimpact the fractured ends.

If on inspection, the roundness of the shoulder is lost, search for abnormal position of the head of the humerus. In dislocations it usually lies in the infraclavicular fossa (anterior), and rarely just posterior inferior to the acromion or its spious process (posterior) of the sublenoid region (inferior) . In

fresh cases of dislocations the finding of depressed contour should be enough to diagnose it. Any attempt to move the shoulder, to note the movement of the head under the palpating fingers, will initiate endless pain and spasm. In the paralytic shoulder, the delotoid mass thins out. the head of the humerus stands prominent much below the acromial process, thereby having a step in between the acromion and the head of the humerus in which the finger can be well insinuated. Atrophy of the deltoid, abnormal mobility of the shoulder (mainly passive) and the 'step sign' are diagnostic paralytic subluxation or dislocation.

**Special Tests :**

**Hamilton Ruler Test** :

In a normal shoulder, a straight ruler cannot touch the acromial process and lateral epicondyle of humerus at the same time because of the prominence of the deltoid bulge, which is supported the the head of humerus. If the support is lost, the ruler can touch both the points (e.g. dislocation of the shoulder, congential absence or iatrogenic excision of the head of humerus; complete paralytic atrophy of the deltoid, as in polio , paralysis; dissolution of humeral head in septic arthritis).

**Callaway's Test :**

The girth from axillary base to shoulder top are symmetrical and same on both sides. If the head of himerus occupies an abnormal position e.g. in dislocation, the girth increases on the affected side.

**Duga's Test :**

Normally, after full flexion at the shoulder the elbow can be brought to near aboutl the mid body plane and the hand to the opposite shoulder top. In dislocation of the shoulder joint, the full flexion of the shoulder cannot be brought to the mid body plane and hand cannot be taken to the opposite shoulder.

**Bryant's Sign :**

In anterior subcoracoid dislocation of the shoulder, the anterior axillary fold looks elongated and seems to be at lower level.

**Test for integrity of the Brachial Plexus :**

Test for the integrity of the brachial plexus is essential as it may be variably damaged in anterior dislocation of shoulder.

Erb's palsy (upper brachial palsy) – look for the typical attitude and test of the muscle supplied by C (see the chapter on peripheral nerve injury).

**Test for integrity of the Axillary Nerve :**

It is manifested by loss of deltoid action i.e. abduction of shoulder (though initiation is possible) and sensory loss over the 'regimental badge' area at upper outer aspect of the arm.

**Radial Nerve:**

Manifested by wrist drop.

**Test for Thoracic inlet syndrome :**

Thia syndrome comprises the pathologies in which there is compression of the subclavin artery and / or lower roots of the brachial plexus e.g. scalenus anticus syndrome, costoclavivular lsyndrome, subclavian aneurysm, cervical ribs. Pancoast tumor, exubearnt callus in fracture clavicle etc.,

**Tests for Bicipital Tenosynovitis :**

i. Yergason's sign patient flexes the elbow and then supinates the forearm against resistance. The resulting forceful contraction of biceps effects distal movement of the tendon and causes pain in the bicipital groove.

ii. The elbow is flexed 90 ° and examiner's three fingers are firmly placed along the antero superior slope of the deltoid bulge (line of bicipital groove); ask the patient to alternately rotate the shoulder externally and internally patient will complain of pain when the inflamed tenosynovitis will pass under the pressing fingers.

**Test for complete Rupture of supraspinatus :**

It is difficult to categorically distinguish pure supraspinatus and other rotator cuff ruptures from any pathology of the subacromial region. However, in complete rupture, a gap may be felt beneath the acromion, which will be tender. Patient cannot initiate active abduction at the shoulder (gleno-humeral joint), but one the arm is passively abducted to about 90 º, he can sustain and further actively abduct the shoulder due to deltoid action.

Incomplete rupture of the supraspinatus and other rotator cuff muscles can be diagnosed by infiltrating local anesthetic in the affected area, which abolishes the pain and spasm, allowing the patient to abduct the shoulder from the very beginning.

**Neer's Impingement Test :**

It is done to differentiate impingement syndrome (mainly subacromial pathology) from 'frozen shoulder' arthritis. Here the clinician prevents scapular rotation with one hand, while with the other hand he raises the affected arm in forced forward flexion and abduction, thus causing the greater tuberosity to impinge against the acromion. Pain is produced in all the above conditions. If the pain is primarily the result of impingement, it can be reduced or eliminated by injecting by injecting 10ml of 1 lignocaine beneath the anterior acromion.

**Apley's Scratch Test:**

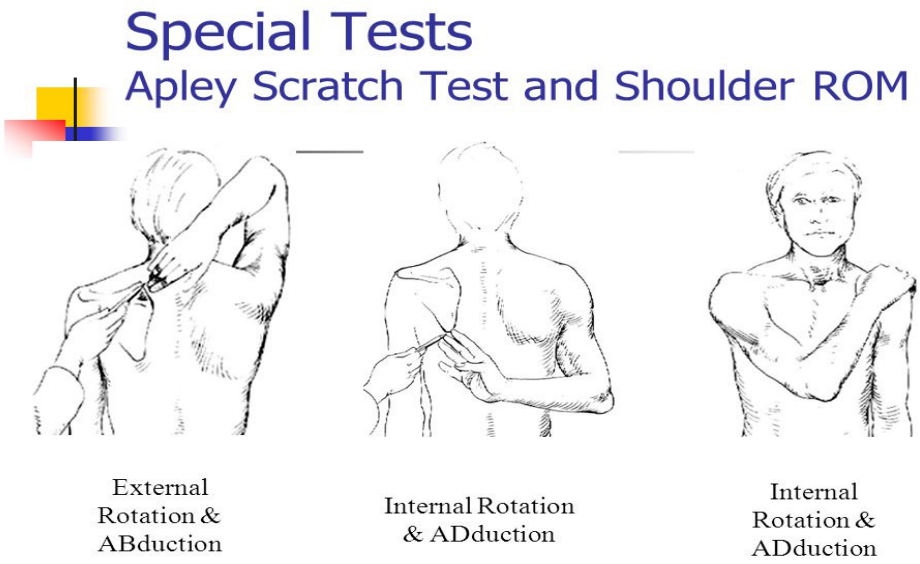
**Purpose** :

Tests for liminations in motions of the upper extremity Each motion is performed bilaterally to compare

**Description:**

**Action 1:**

The subject is instructed to touch the opposite shoulder with his/ her hand. This motion check Glenohumeral adduction, Internal rotation, horizontal adduction and Scapular protraction.




**Action 2:**

The subject is instructed to place his/ her arm over head and reach behind the neck to touch his/ her upper back. This motion check Glenohumeral abduction, external rotation and scapular upward rotation and elevation.

**Action 3:**

The subject puts his/ her hand on the lower back and reaches upwards as far as possible. this motion checks internal rotation and scapular retraction with downward rotation

**DIFFERENTIAL DIAGNOSIS:**

- Locked posterior and anterior dislocation
- Subacromial impingement
- Rotator cuff lesions

**Complications :**

Later intensive physical therapy with pain mediation is given. The complications of manipulation is humeral fracture, dislocation, rotator cuff lesion and biceps tendon rupture.

Beacon Bayley have cautioned this and have suggested accurate positioning of the surgeon's hand, so that only a short leverage is appliec to the humerus.

Edmondas and Taylor (1982) have shown in their series that manipulation with intraarticular steroid and physical therapy produces good results in case of adhesive capsulitis.

**INVESTIGATIONS**

Besides the routine X-ray, haematological investigations and urine analysis, some special investigations may also be required according to indications.

**X-ray :**

It is of great importance in any shoulder affection. It is always useful to take a comparative X-ray of the opposite shoulder. The shoulder girdle must be fully exposed along with a minimum of the upper one-third of the arm. In suspected referred pain around the shoulder, X-ray of cervical is spine is necessary.

Antero-posterior X-ray patient lies supine with the arm adducted. The plate is kept behind the shoulder and beam in focused from the front at the shoulder level. With any suspicion of subluxation / dislocation of the acromio - clavicular joint, antero-posterior X-ray should be taken, while the patient stands, keeping his upper limbs hanging by the side of his chest, with some weight tied to his hand. Standing position X-ray should also be taken in case of paralyzed shoulder.

Lateral axillary (trans axillary) view - the shoulder is abducted to about 90 º and the plate is kept on the shoulder top. The X-ray is shot through the base of the axilla.

**Special Antero-posterior projection :**

The special X-ray projection demonstrates the Hill-Sach's in recurrent dislocation of the shoulder.

While shoulder is abducted about 30º and internally rotated about 40º to 60 º, the plate is placed behind the shoulder and the beam is shot from the front at the shoulder level. In certain recurrent anterior dislocations, a

radiological step can be delineated on the postero-supero-lateral aspect of the head of the humerus (Hill-Sach's lesion or Broca lesion), presumably due to repeated compression over the head by impaction against the anterior marging of the glenoid, though it may also be congential defect. A similar defect may be seen on the antero medial sector of the head in recurrent posterior dislocation of the shoulder.

**ARTHROGRAM:**

Arthrogram will show lessof the normally loose dependent fold of the joint. The dye does not fill in to this dependent told. Also the amount of the contrast material that can be injected into the joint is reduced.

**ARTHROSCOPY:**

Arthroscopically, adhesive capsulities can be divided into four stages.

**Stage I (pre adhesion stage)**

This stage mimics impigment syndrome or rotator cuff lesion. Clinically this stage shows signs and symptoms of impingement syndrome. There is minimal restriction of motion. Arthroscopically, erythematous fibrinous pannus is seen over the synovium.

**Stage II (acute adhesive synovitis)**

Clinically there is severe less of motion in all planes with pain in all ranges of motion. Arthroscopically , the synovium appears red, angry and thickened. It can visualize adhesions growing across the dependent told in to the humeral head. There is less of normal interval between the humeral head and biceps tendon.

**Stage III (maturation of adhesion)**

This is also called as the stage of pink synovitis. Here the erythematous panner over the synovium appears pale. The dependent fold is reduced to half of its normal size. Humeral head remains pressed against the glenoid.

**Stage IV ( chronic adhesion phase)**

In this stage, there is no synovitis. The dependent fold is severely lost. Motion is at its worst.

**TREATMENT:**

Treatment varies according to the stage of the disease.

**Painful phase:**

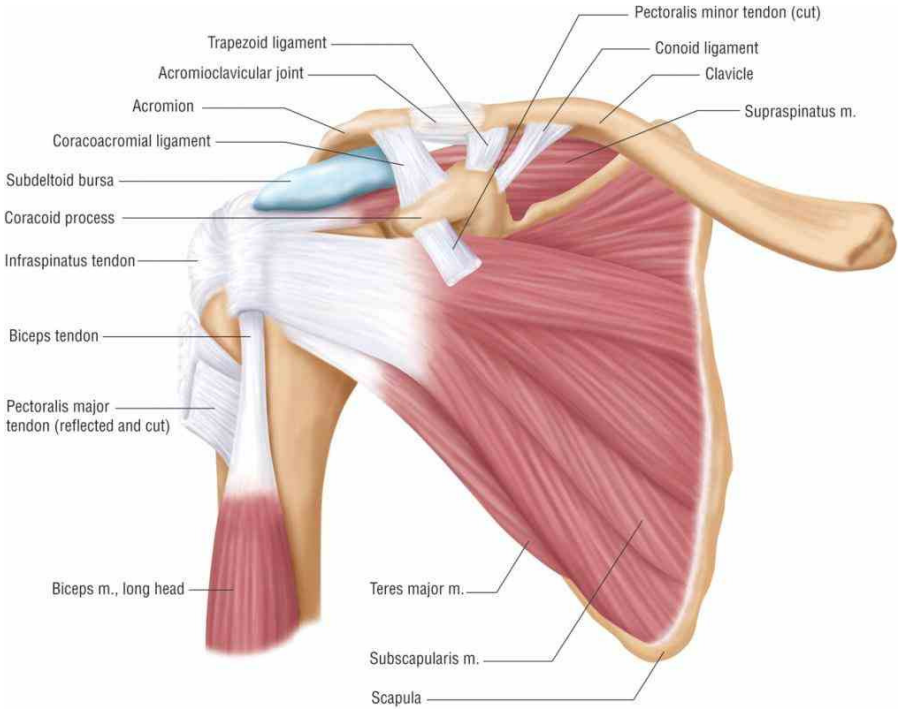
Anti inflammatory drug are effective and a short course of systemic steroids may be needed for patients with severe pain, physiotheraphy is effective during this stage

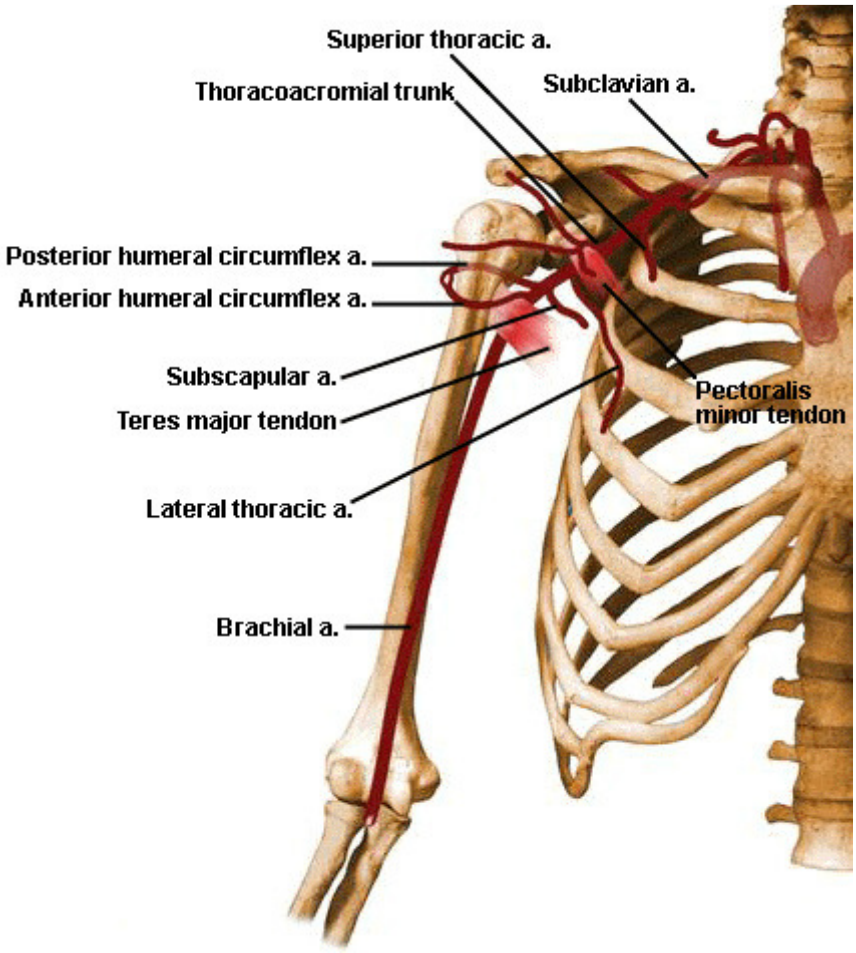
**Stiff phase:**

During this phase, physiotheraphy to improve the range of movement is occasionally helpfull by relief is unpredictable.

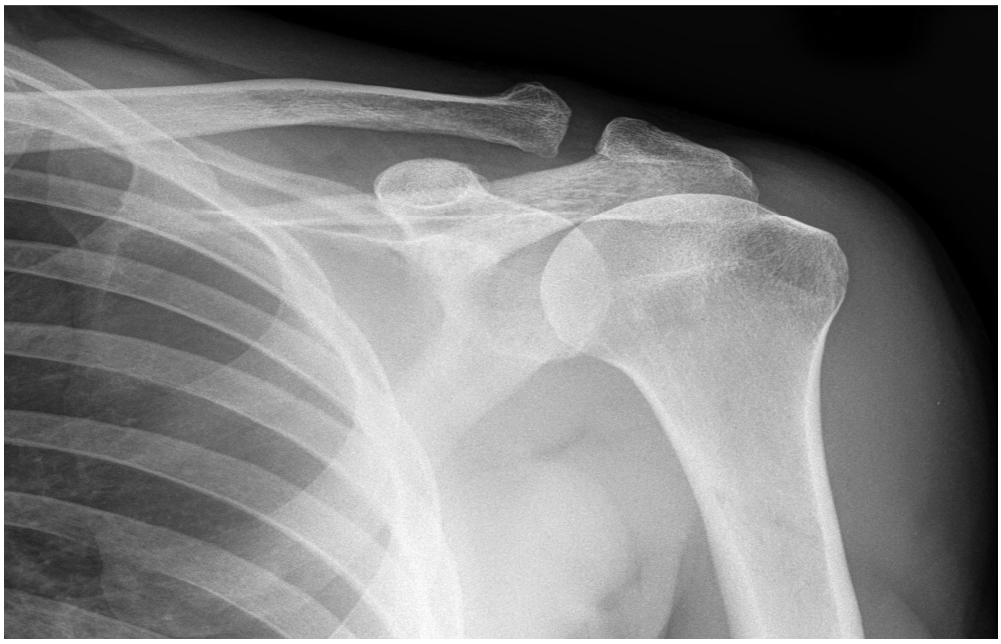
**Recovery phase:**

Physiotherapy or manipulation under anaesthetic may produce an increase in movement arthoscopic surgery to release the capsule has been shown to speed up the relieve.

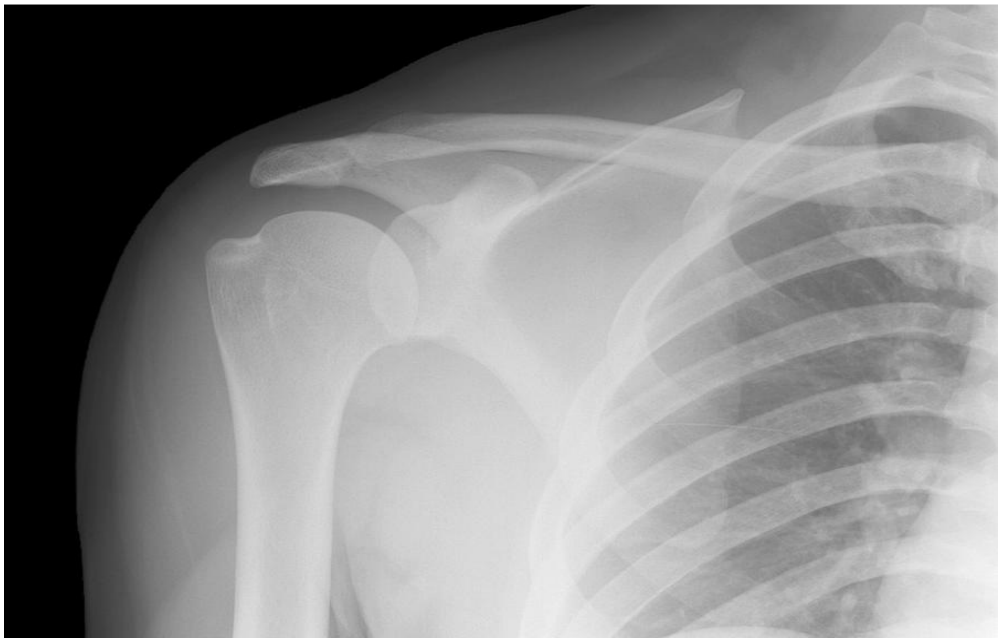

Pectoralis minor tendon (cut)
Trapezoid ligament
Conoid ligament
Acromioclavicular joint
Clavicle
Acromion
Supraspinatus m.
Coracoacromial ligament
Subdeltoid bursa
Coracoid process
Infraspinatus tendon
Biceps tendon
Pectoralis major tendon (reflected and cut)
Biceps m., long head
Teres major m.
Subscapularis m.
Scapula


Superior thoracic a.
Thoracoacromial trunk
Subclavian a.
Posterior humeral circumflex a.
Anterior humeral circumflex a.
Subscapular a.
Teres major tendon
Pectoralis minor tendon
Lateral thoracic a.
Brachial a.

**SHOULDER X-RAY LEFT (AP VIEW)**



**SHOULDER X-RAY RIGHT (AP VIEW)**



# MATERIALS AND METHODS

The clinical study on kumba vatham was carried out in the post graduate sirappu maruthuvam department of Government siddha medical college and Palayamkottai In these study 40 patients (who are selected by inclusion and exclusion criteria) were treated as OP and IP patients.

**Selection of the patients:**

**Age:**

30 years to 60 years

**Sex:**

Male and Female

**The history details were taken from the patient about:**

- Occupation.
- Social economic status.
- Psychological condition.

**INCLUSION CRITERIA :**

- Age : 30-60 years
- Sex : Both Male and Female
- Patient having main symptoms of shoulder joint pain radiating towards upper arm and forearm, numbness, restricted movement of upper limb, loss of abduction and forward flexion followed by stiffness of the shoulder joints.
- Patient willing to sign the informed consent stating that he / she will consciously stick to the treatment during 20 days.
- Willing for doing laboratory investigations and X-Ray, imaging.
- Willing to cooperate with the proper clinical examination.
- Controlled Diabetes mellitus
- Controlled hypertension

**EXCLUSION CRITERIA :**

- Rheumatoid arthritis
- Ischaemic heart diseases
- Pregnancy and lactation

- Recent shoulder dislocation
- Recent shoulder fracture

**TESTS AND ASSESMENTS :**

- Clinical assessment
- Siddha assessment
- Laboratory Investigations
- Radiological assessment

**CLINICAL ASSESSMENT :**

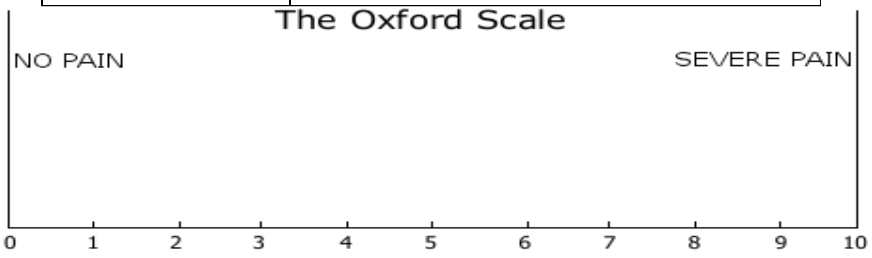
- Acute shoulder joint pain
- Benumbed feeling
- Wasting in the shoulder region and arms
- Restricted movement of the upper limbs
- Loss of abduction
- Loss of forward flexion
- Stiffness of the shoulder joint
- Dizziness

**PAIN ASSESMENT :**

**OXFORD SHOULDER SCORE :**

Interpreting the Oxford Shoulder Score

| | |
|---|---|
| Score 0 to 19 | Indicate sever shoulder arthritis |
| Score 20 to 29 | Indicate moderate to severe |
| Score 30 to 39 | Indicate mild to moderate |
| Score 40 to 48 | Indicate satisfactory joint function |



**SIDDHA ASSESSMENT:**

1. Naadi
2. Sparisam
3. Naa
4. Niram
5. Mozhi
6. Vizhi
7. Malam
8. Moothiram
    - Neerkkuri
    - Neikkuri

**Diagnosis:**

The diagnosis was made by following Siddha diagnosis methods Nilam,Kaalam,Pulanal arithal Poriyal arithal vinaathal Mukkutra Nilaigal Udal Thathukal Nilai and Envagai thervugal,and the diagnosis of Kumba vatham were obtained which correlated with diagnosis of Peri arthritis by the X-Ray findings.

## LABORATORY INVESTIGATIONS:

### Blood:

- TC
- DC
- ESR
- Hb
- Blood Sugar

    Fasting

    Random

    Post prandial

- Blood urea
- Serum Creatinine
- Serum Cholesterol

### Urine:

- ✓ Albumin
- ✓ Sugar
- ✓ Deposits

## SPECIFIC INVESTIGATIONS:

### RADIOLOGICAL INVESTIGATION:

- ✓ X- Ray: Shoulder joint AP view and lateral view.
- ✓ ECG in selected cases
- ✓ Arthrogram and MRI in required cases

**Treatment**

On the first day of treatment 15 ml of Vellai ennai was given at morning with hot water was given.

All the patients were treated with the following medicines.

**1.Santhira pragasa mathirai** (Internal)

1 tablet(130 mg) with Chukku kudineer

**2. Sembai thylum:** 30ml (external)

**As External application**

Otradam and fomentation was given as a complementary therapy for Ip patients. All the patients were advised to follow dietary regimen (or) pathiyam.

The Bio-Chemical analysis was done in the Biochemistry Department and Pharmacological analysis was done in the Pharmacological laboratory of KMCH college of Pharmacy, Coimbatore.

# RESULTS AND OBSERVATION

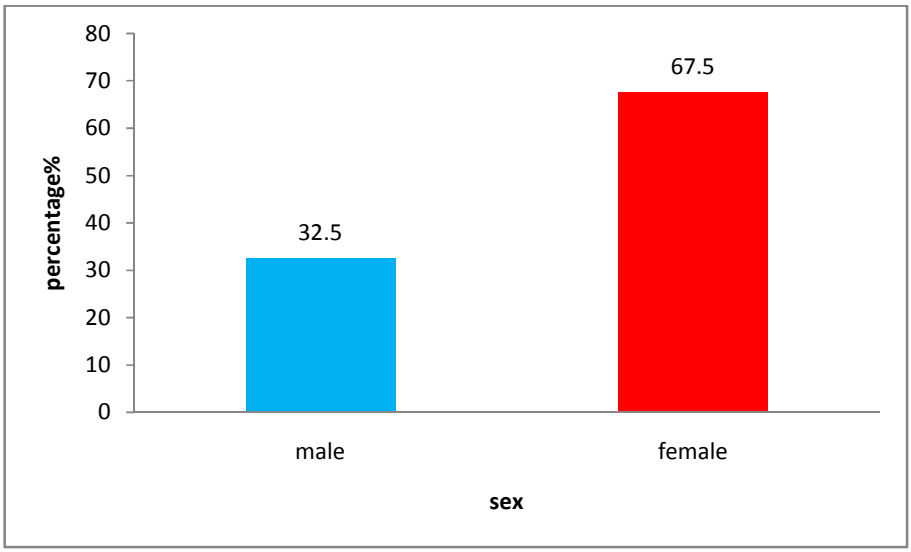
For the clinical study 40 patients were selected and treated in PG-III Sirappu Maruthuvam Department, Government Siddha Medical College and Hospital, Palayamkottai. Results were observed with respect to the following criteria.

1. Sex distribution
2. Age distribution
3. Kaalam
4. Thinai
5. Paruva kaalam
6. Occupation
7. Socio-Economical status
8. Disturbance in vadha
9. Disturbance in pitha
10. Disturbance in kabha
11. Envagai Thervugal
12. Udal Thathukkal
13. Duration of illness
14. Mode of onset
15. Associated disease
16. Naadi
17. Nei kuri
18. Clinical manifestations
19. Duration of treatment
20. Assesment the effect of therapy
21. Effect of complementry therapy massage
22. Effect of complementry therapy Ottradam
23. Effect of therapy trial drug alone

**1.SEX DISTRIBUTION**

**Table 1. Illustrates sex distributions in relative percentage.**

| S.no | Sex | No. of cases | | Percentage |
|---|---|---|---|---|
| | | Op | Ip | |
| 1. | Male | 8 | 5 | 32.5 |
| 2. | Female | 15 | 12 | 67.5 |
| 3. | Total | 23 | 17 | 100 |



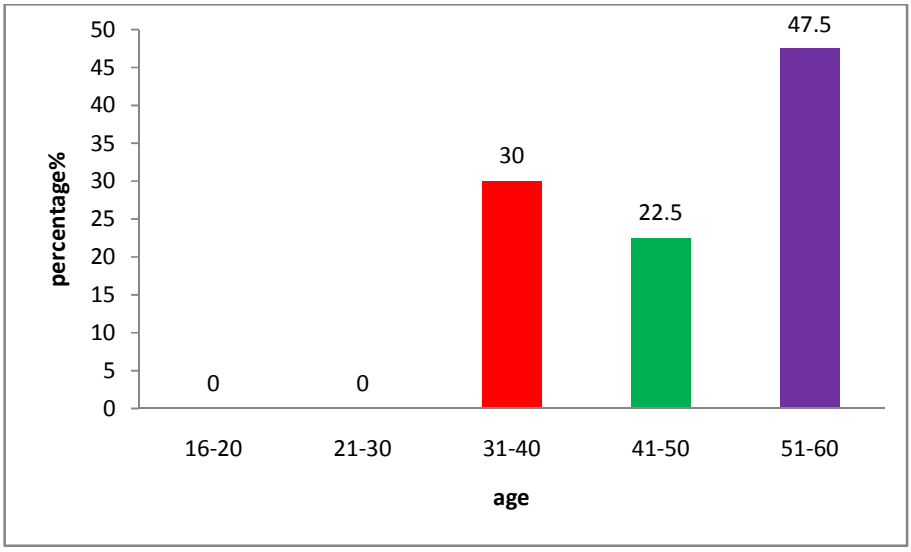

**Inference :**

Out of 40 patients, 32.5% were males and 67.5% were females.

**2. AGE DISTRIBUTION**

**Table2. Illustrates the age distribution and its relative percentage**

| S.no | Age | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | 16 – 20 | - | |
| 2 | 21 – 30 | - | |
| 3 | 31 – 40 | 12 | 30 |
| 4 | 41 – 50 | 9 | 22.5 |
| 5 | 51 - 60 | 19 | 47.5 |
| | Total | 40 | 100 |



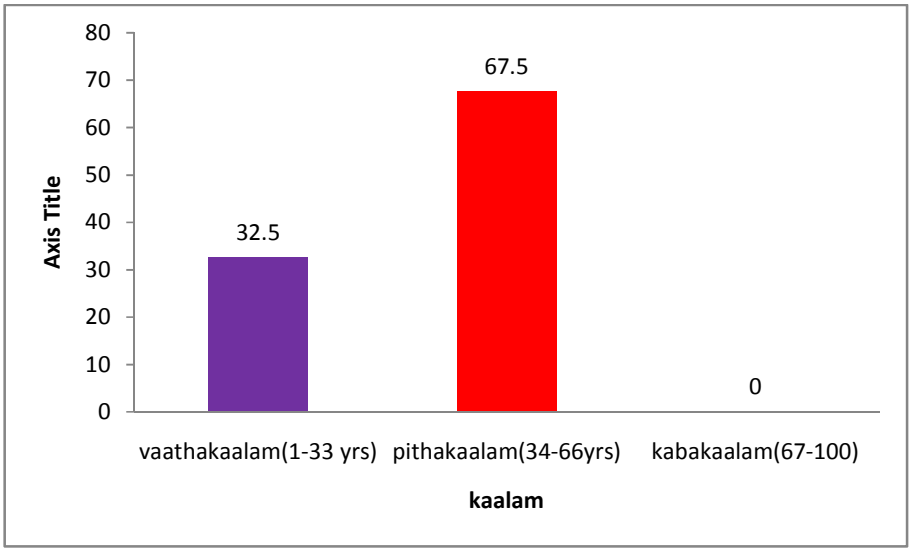

**Inference**

Among 40 patients, most of the age group affected were 51-60 (47.5%).

**3. KAALAM**

**Table 3. Illustrates the life span and the relative percentage**

| S.no | kaalam | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Vatha kaalam(1-33yrs) | 13 | 32.5 |
| 2 | Pitha kaalam(34-66yrs) | 27 | 67.5 |
| 3 | Kaba kaalam(67-100yrs) | - | - |




**Inference :**

Out of 40 patients,

32.5% of cases were in the vadha kaalam

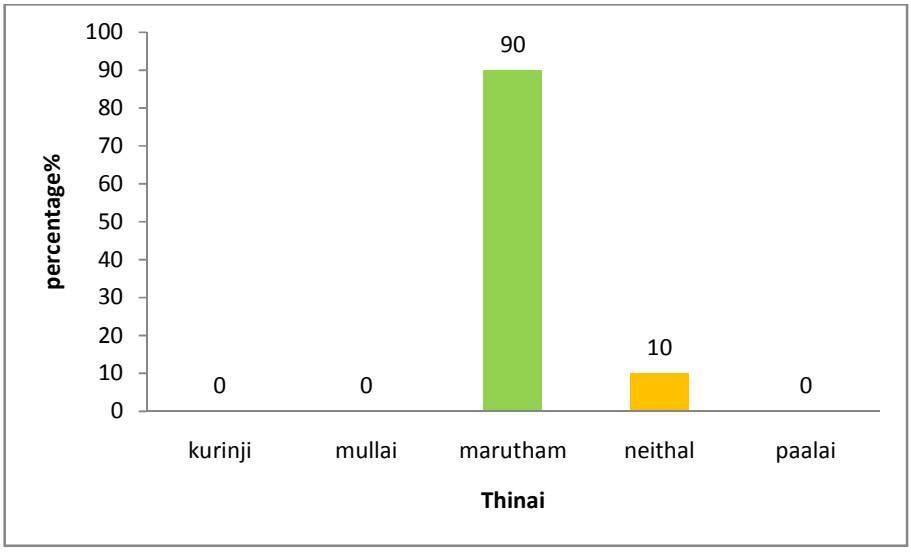
67.5% of cases were in the pitha kaalam

0 % of cases were in the kabha kaalam

**4. THINAI (THE HABITAT OF THE PATIENTS)**

**Table 4. Illustrates the thinai and its percentage**

| S.no | Thinai or Land | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Kurinji | - | - |
| 2 | Mullai | - | - |
| 3 | Marutham | 36 | 90 |
| 4 | Neithal | 4 | 10 |
| 5 | paalai | - | - |
| 6 | Total | 40 | 100 |



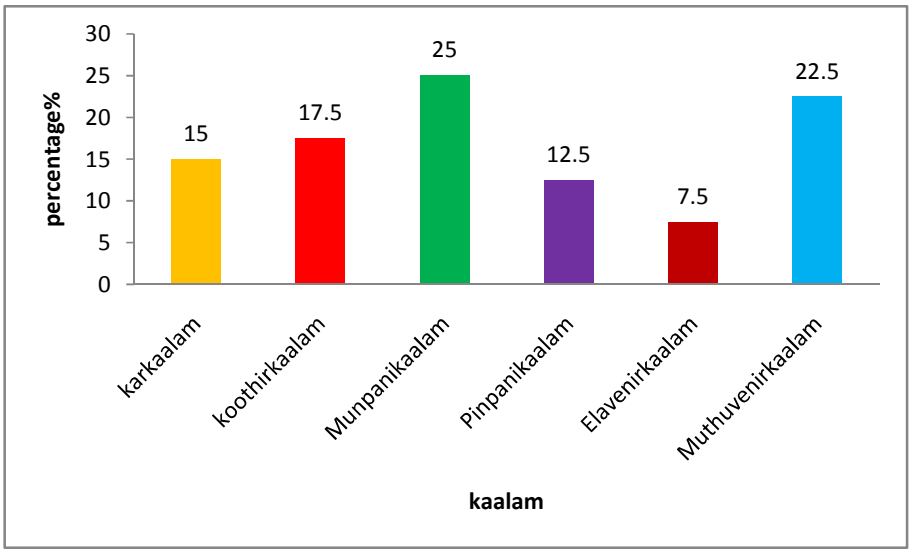

**Inference**

Among the 40 patients 90% were from marutham and 10 % cases were from Neithal thinai.

**5. PARUVAKALAM**

**Table 5. Illustrate the paruvakalam and its percentage**

| S.no | Paruvakalam | Month | No. of patients | Percentage(%) |
|---|---|---|---|---|
| 1 | Kaarkalam | Avani-puratasi (15 aug – 14 oct) | 6 | 15 |
| 2 | Koothirkaalam | Ippasi-karthigai (15 oct – 14 dec) | 7 | 17.5 |
| 3 | Munpanikaalam | Margazhi-thai (15 Dec – 14 feb) | 10 | 25 |
| 4 | Pinpanikaalam | Maasi-panguni (15 feb – 14 apr) | 5 | 12.5 |
| 5 | Elaveenirkaalam | Chitthirai-vaigasi (15 apr – 14 jun) | 3 | 7.5 |
| 6 | muthuvenirkaalam | Aani-aadi (15 jun– 14 aug) | 9 | 22.5 |



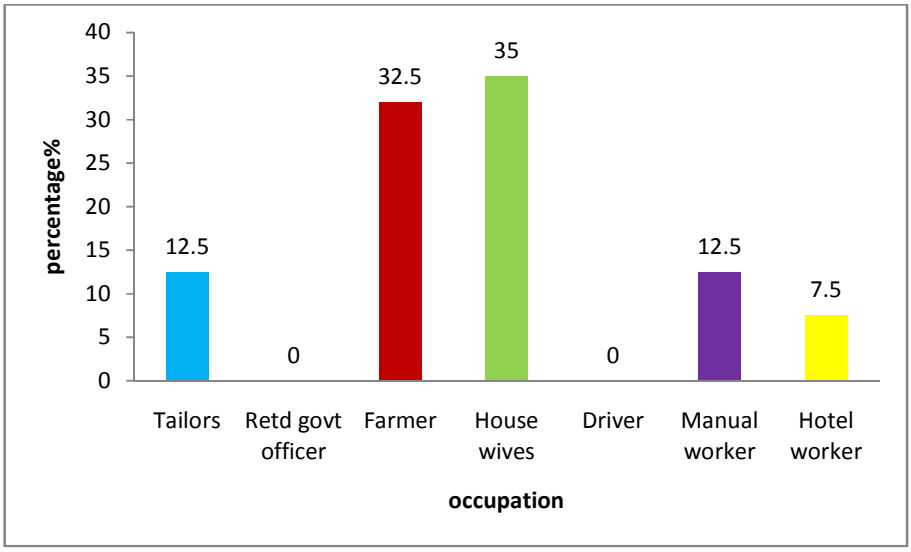

**Inference**

Among 40 cases, 25% of patients were affected in Munpani kaalam 12.5% of patients were affected in pinpani kaalam and 22.5% were affected in mudhuvenirkaalam patients and 17.5% of patients were affected in Koothir kaalam 15% were affected in kaarkalam patients and 7.5% patients were affected in Elavenil kaalam .

**6. OCCUPATION**

**Table 6. Illustrates the occupation and its percentage**

| S.no | Occupation | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Tailor | 5 | 12.5 |
| 2 | Retd govet officer | - | - |
| 3 | Farmer | 13 | 32.5 |
| 4 | House wife | 14 | 35 |
| 5 | Driver | - | - |
| 6 | Manual worker | 5 | 12.5 |
| 7 | Hotel | 3 | 7.5 |



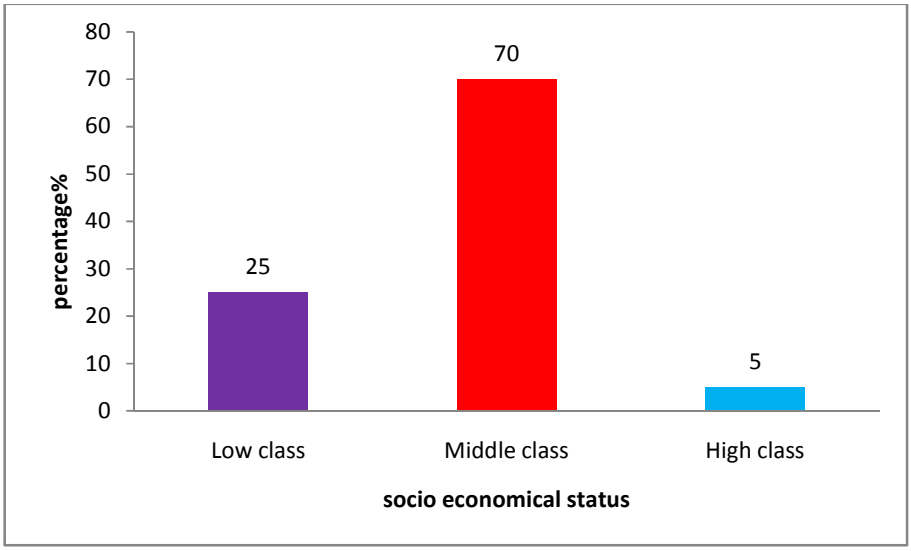

**Inference**

Out of 40 cases, in this study the rate of incidence is higher in former (32.5%) , house wife (35%) , manual worker (12.5%), Tailors(12.5%), hotel worker (7.5%)

**7. SOCIO- ECONOMICAL STATUS**

**Table 7. Illustrate socio-economical status and its percentage**

| S.no | Socio - Economical status | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Low class | 10 | 25 |
| 2 | Middle class | 28 | 70 |
| 3 | High class | 2 | 5 |



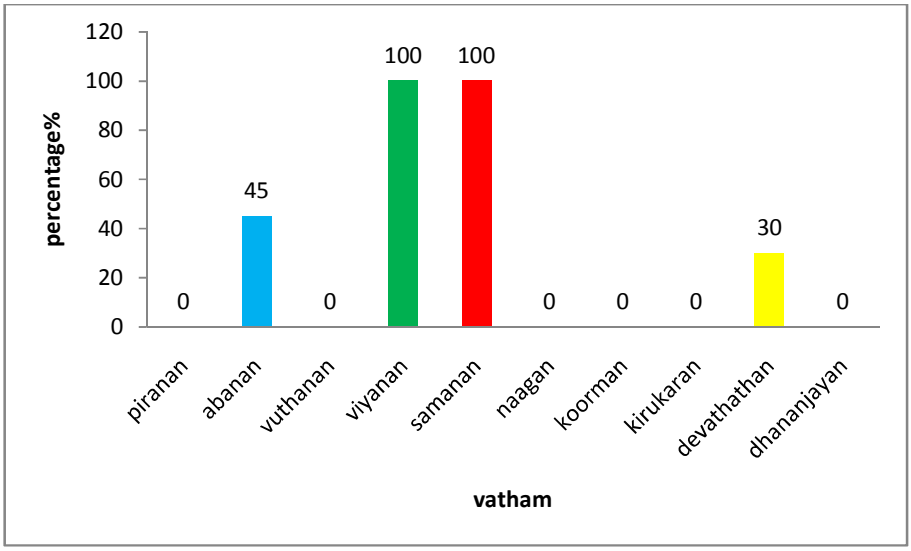

**Inference**

The above study consisted of 5% of cases from rich class, 70% of cases from middle class and 25%% of low class.

**8. DISTURBANCE IN VATHAM**

**Table 8. Illutrates the disturbance in vatham and its percentage**

| S.no | Vatham | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Piranan | - | - |
| 2 | Abanan | 18 | 45 |
| 3 | Vudhanan | - | - |
| 4 | Viyanan | 40 | 100 |
| 5 | Samanan | 40 | 100 |
| 6 | Naagan | - | - |
| 7 | Koorman | - | - |
| 8 | Kirukaran | - | - |
| 9 | Thevathathan | 12 | 30 |
| 10 | Thananjayan | - | - |



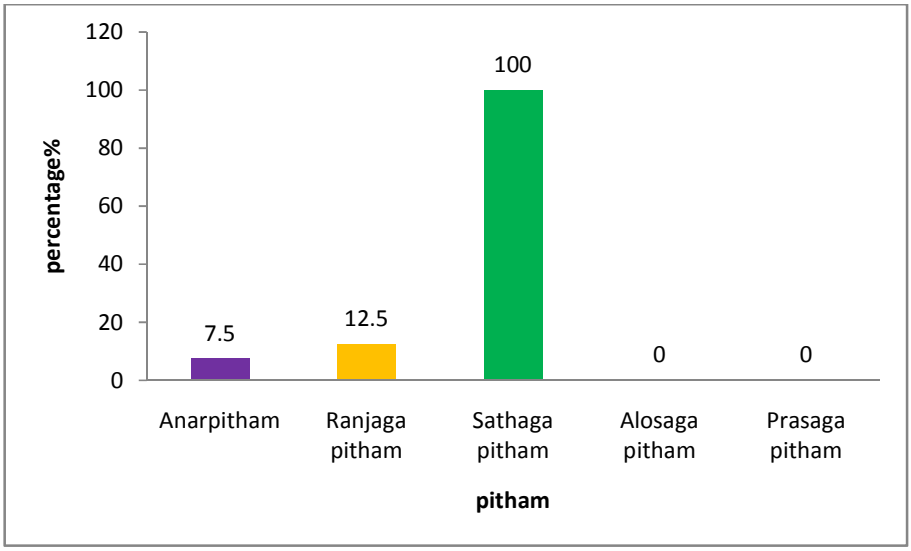

**Inference**

Among the 10 types of vatha, Samanan and viyanan were affected in all the cases (100%). Abanan was noted to be deranged in 45% and Devathathan was abnormal in 30%.

**9. DISTURBANCES IN PITHAM**

**Table 9. Illustrates the disturbances in pitham and its percentage**

| S.no | Pitham | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Anarpitham | 3 | 7.5 |
| 2 | Ranjagapitham | 5 | 12.5 |
| 3 | Sathagapitham | 40 | 100 |
| 4 | Aalosagapitham | - | - |
| 5 | Pirasagapitham | - | - |



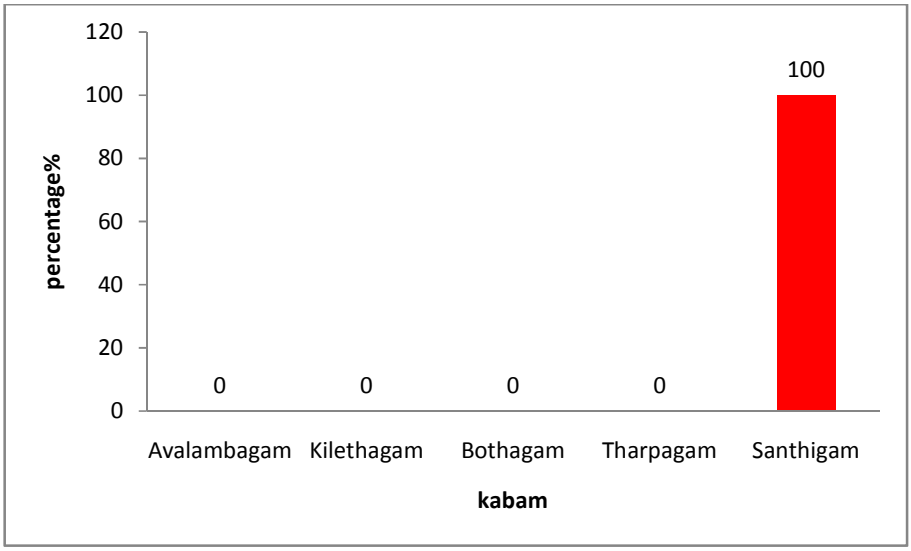

**Inference**

The five types of pitham were analyzed in all 40 cases, Sathaga pitham was altered in all cases (100%) evidenced as difficulty in handling their regular duties because of pain in shoulder and radiating pain in upper limb. Ranjaga pitham was affected in12. 5% patients denoting low haemoglobin count.

**10. DISTURBANCES IN KABAM**

**Table 10. Illustrates the disturbances in kabam and its percentage**

| S.no | kabam | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Avalambagam | - | - |
| 2 | Kilethagam | - | - |
| 3 | Pothagam | - | - |
| 4 | Tharpagam | - | - |
| 5 | Santhigam | 40 | 100 |




**Inference**

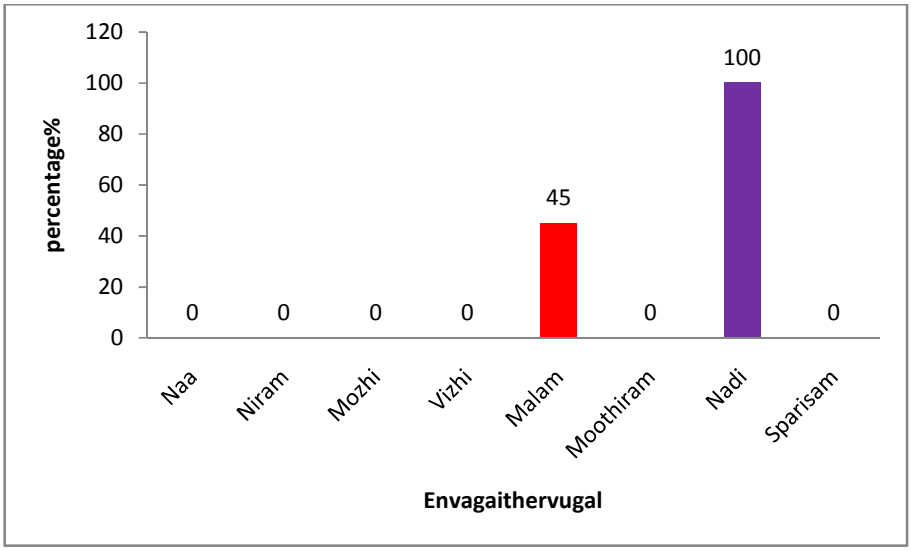
Santhigam was observed to be affected in all the cases.

**11.DIAGNOSTIC PARAMETERS**

**ENVAGAI THERVUGAL**

**Table 11. Illuestrate the envagaithervugal and its percentage**

| S.no | Envagai thervugal | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Naa | | |
| 2 | Niram | | |
| 3 | Mozhi | | |
| 4 | Vizhi | | |
| 5 | Malam | 18 | 45 |
| 6 | Moothiram | | |
| 7 | Naadi(thontha naadi) | 40 | 100 |
| 8 | Sparisam | | |



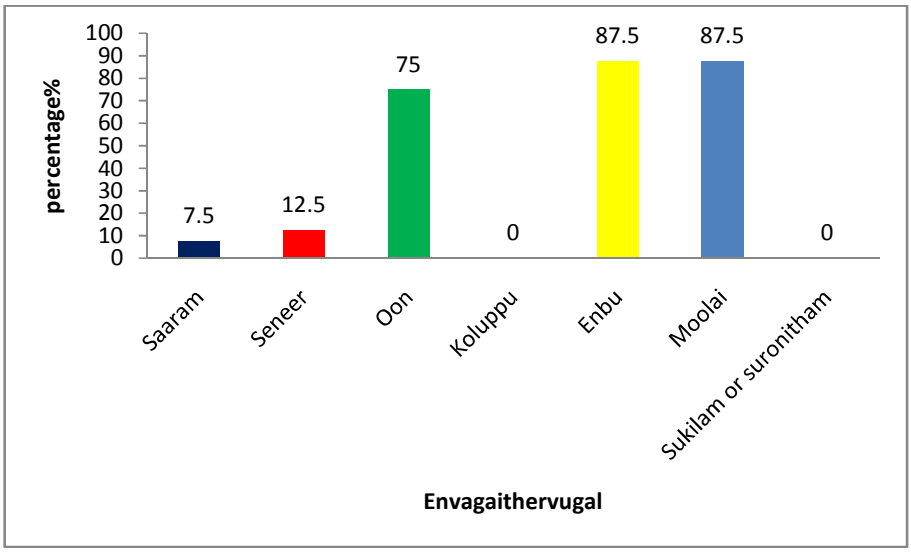

**Inference**

It was learnt during the study that thontha naadi was noted in all 40 cases, malam was affected in 45% of cases

**12. UDAL THATHUKKAL**

**Table 12. Illustrates the udal thathukkal and its percentage**

| S.no | Udal kattukal | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | saaram | 3 | 7.5 |
| 2 | senneer | 5 | 12.5 |
| 3 | oon | 30 | 75 |
| 4 | kozhuppu | 0 | 0 |
| 5 | enbu | 35 | 87.5 |
| 6 | Moolai | 35 | 87.5 |
| 7 | Sukkilam / suronitham | 0 | 0 |



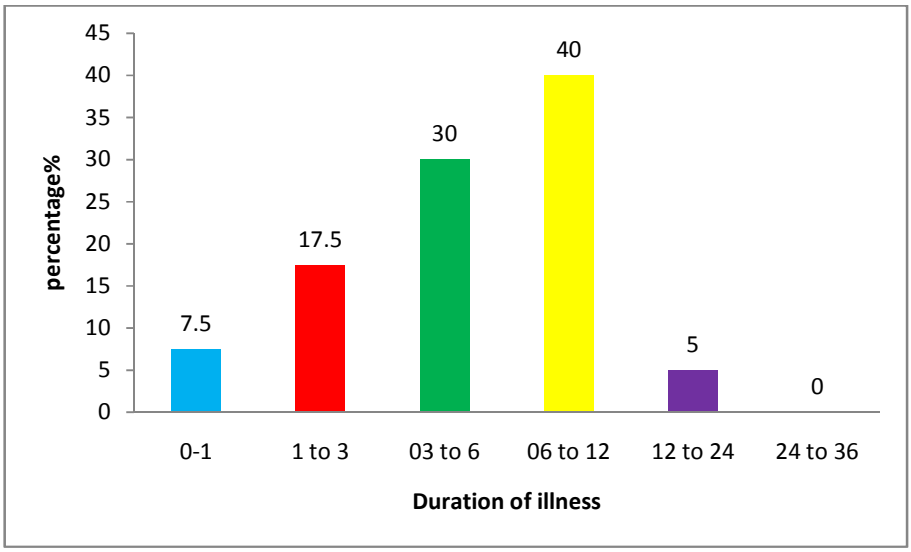

**Inference**

It was diagnosed during the study all the udal kattugal affected in all

## 13. DURATION OF ILLNESS BEFORE STARTING TREATMENT

**Table 13. Illustrates duration of illness before starting treatment and its percentage**

| S.no | Duration of illness (in months) | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | 0 - 1 | 3 | 7.5 |
| 2 | 1 - 3 | 7 | 17.5 |
| 3 | 3 - 6 | 12 | 30 |
| 4 | 6 - 12 | 16 | 40 |
| 5 | 12 - 24 | 2 | 5 |
| 6 | 24 - 36 | - | - |



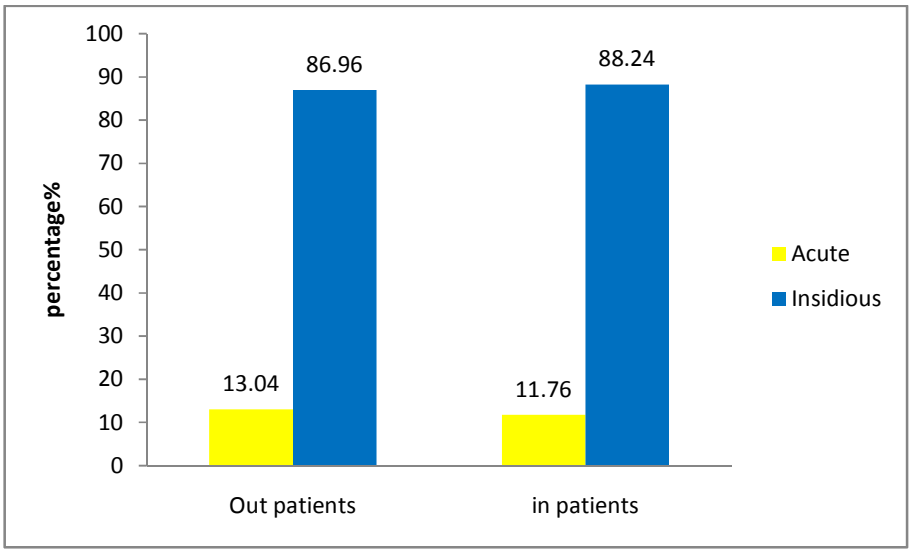

**Inference**

Most of the patients have the duration of illness is 6 – 12 months.

**14. MODE OF ONSET**

**Table 14. Illustrates the mode of onset and its percentage**

| S.no | Mode of onset | Out patients | | In patients | |
|---|---|---|---|---|---|
| | | No.of cases | percentage | No.of cases | percentage |
| 1 | Acute | 3 | 13.04 | 2 | 11.76 |
| 2 | Insidious | 20 | 86.96 | 15 | 88.24 |



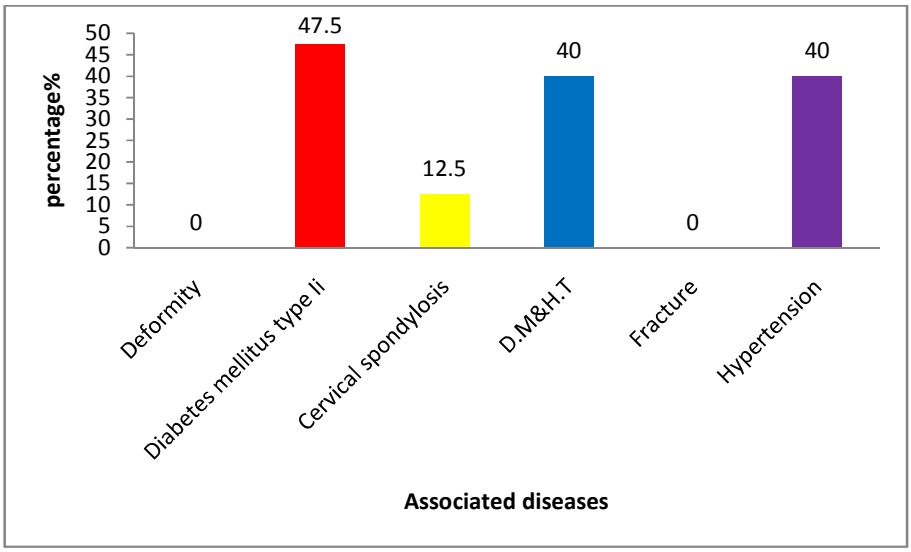

**Inference**

Mode of onset is insidious in 88.24% cases

**15. ASSOCIATED DISEASES**

**Table 15. Illustrates the associated diseases and its percentage**

| S.no | Associated diseases | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Deformity | - | - |
| 2 | Diabetes mellitus (type2) | 19 | 47.5 |
| 3 | Cervical spondylosis | 5 | 12.5 |
| 4 | D.M & H.T | 16 | 40 |
| 5 | Fracture | - | - |
| 6 | hypertension | 16 | 40 |



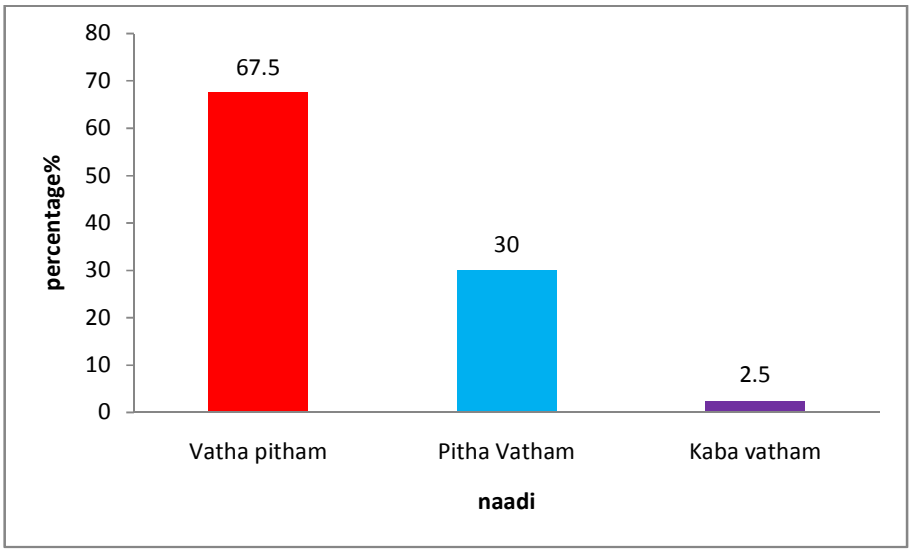

**Inference**

Most of the patients have the associated features is diabetes mellitus 47.5%

**16. NAADI**

**Table 16. Illustrates the naadi and its percentage**

| S.no | parameters | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Vatha pitham | 27 | 67.5 |
| 2 | Pitha vatham | 12 | 30 |
| 3 | Kaba vatham | 1 | 2.5 |



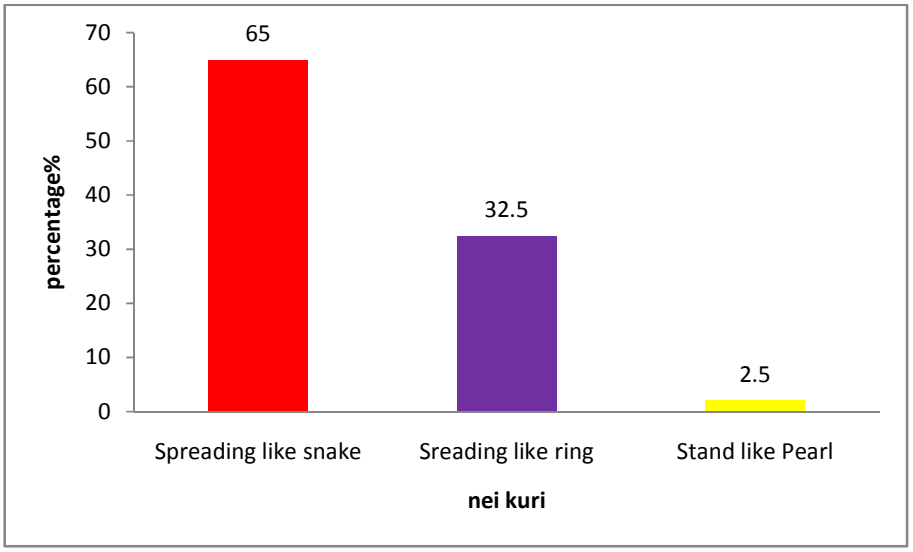

**Inference**

It was learnt during the study that thontha naadi was noted in all 40 cases, malam was affected in 45% of cases

**17. NEIKURI REFERENCES**

**Table 17. Illustrates the neikuri references and its percentage**

| S.no | neikuri | No. of patients | Percentage(%) |
|---|---|---|---|
| 1 | Vatham – aravena neendathu | 26 | 65 |
| 2 | Pitham – aazhipol paraviyathu | 13 | 32.5 |
| 3 | Kabam – muththothu nitral | 1 | 2.5 |



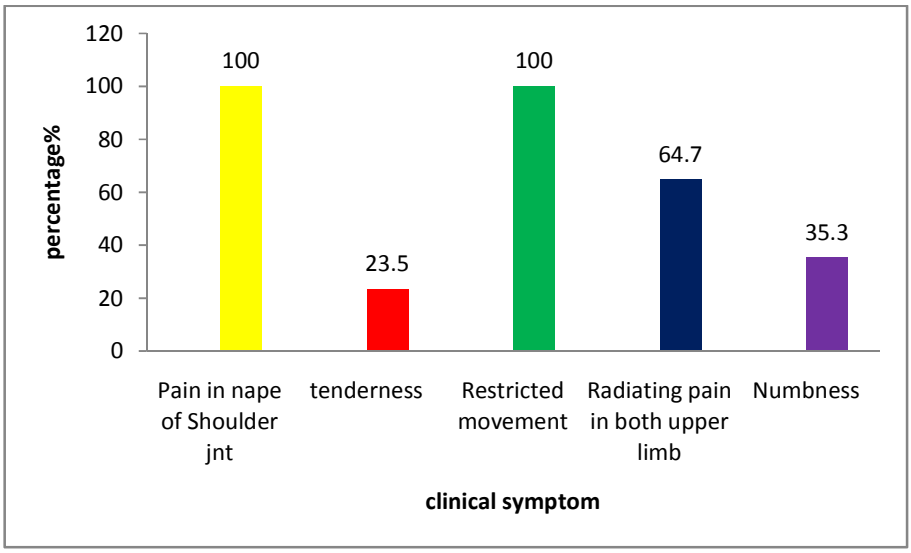

**Inference**

In neikuri analysis 65 % of the cases presented with vatha neer, 32.5% with kaba neer, 2.5% with pitha neer

## 18. CLINICAL MANIFESTATIONS

**Table 18. Illustrates the clinical manifestations and its percentage**

| s.no | Sign and symptoms | Out patients | | In patients | |
|---|---|---|---|---|---|
| | | No.of cases | percentage | No.of cases | percentage |
| 1 | Pain in shoulder joint | 23 | 100 | 17 | 100 |
| 2 | Tenderness | 7 | 30.43 | 4 | 23.5 |
| 3 | Restricted movement | 23 | 100 | 17 | 100 |
| 4 | Radiating pain in the both upper limb | 12 | 52.2 | 11 | 64.7 |
| 5 | Numbness | 9 | 39.1 | 6 | 35.3 |



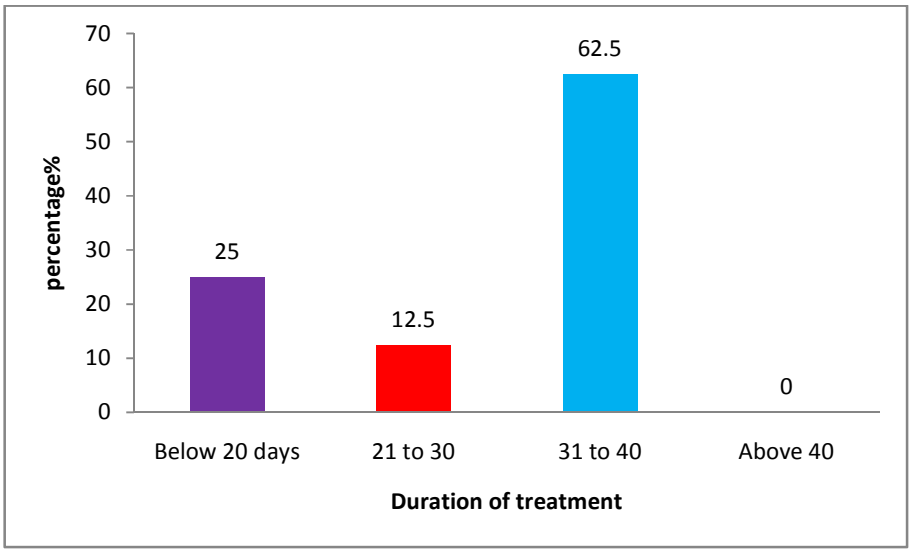

### Inference

It was noted that, clinical manifestations like pain in the shonlder, restriction of movements and radiation of pain to other parts were remarkably reduced after treatment when compared to that of before treatment, Numbness and tenderness showed moderate reduction after treatment.

**19. DURATION OF TREATMENT**

**Table 19. Illuestrates the assessment of therapy and its percentage**

| S.no | Duration of treatment | No. of patients | Percentage |
|---|---|---|---|
| 1 | Below 20 days | 10 | 25 |
| 2 | 21 – 30 days | 5 | 12.5 |
| 3 | 31 – 40 days | 25 | 62.5 |
| 4 | Above 40 days | - | - |



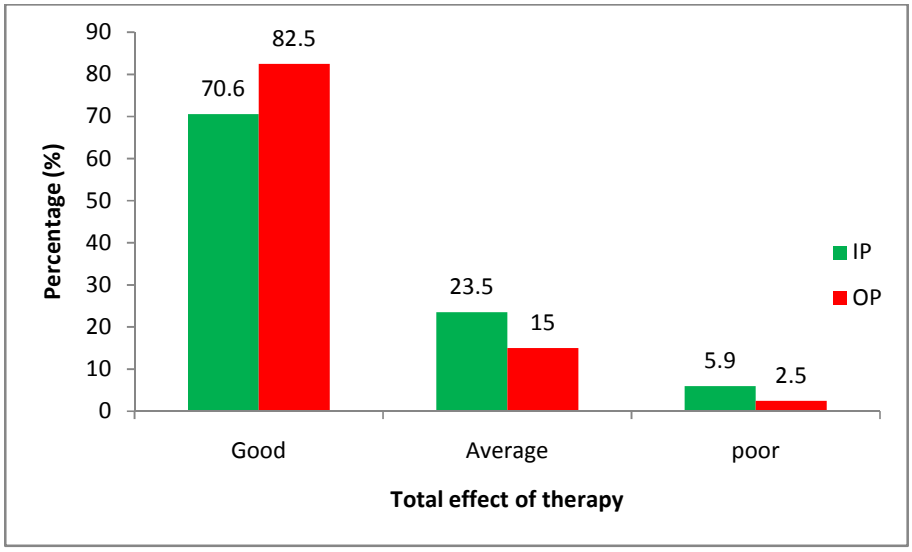

**Inference**

Most of the patients treated in 31 – 40 (62.5%) days and give a good improvement

## 20. ASSESSMENT OF THE EFFECT OF THERAPY

**Table 20. Illustrates the assessment the of the effect of therapy and its percentage**

| S.no | Grade | No. of patients(Ip) | Percentage | No. of patients(Op) | Percentage |
|---|---|---|---|---|---|
| 1 | Good | 12 | 70.6 | 21 | 82.5 |
| 2 | Average | 4 | 23.5 | 2 | 15 |
| 3 | poor | 1 | 5.9 | - | 2.5 |

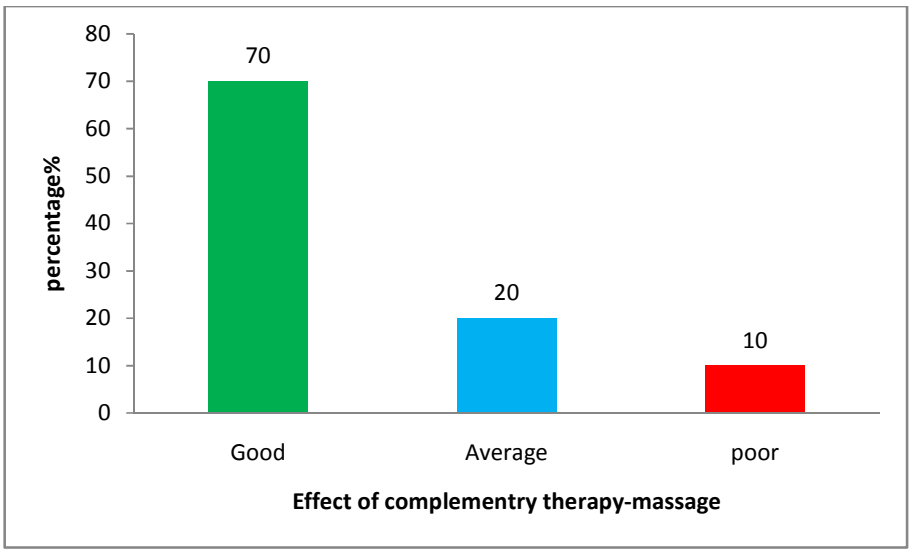



### Inference

Administration of trial drug along with complementary therapies had a good response 82.5% average with 15% and mild with 2.5%

**Table 21. Effect of Complementory therapy along with trail drug (Massage)**

| S.no | Effect of therapy | No. Of patients | Percentage(%) |
|---|---|---|---|
| 1 | Good | 7 | 70 |
| 2 | Moderate effect | 2 | 20 |
| 3 | Mild effect | 1 | 10 |

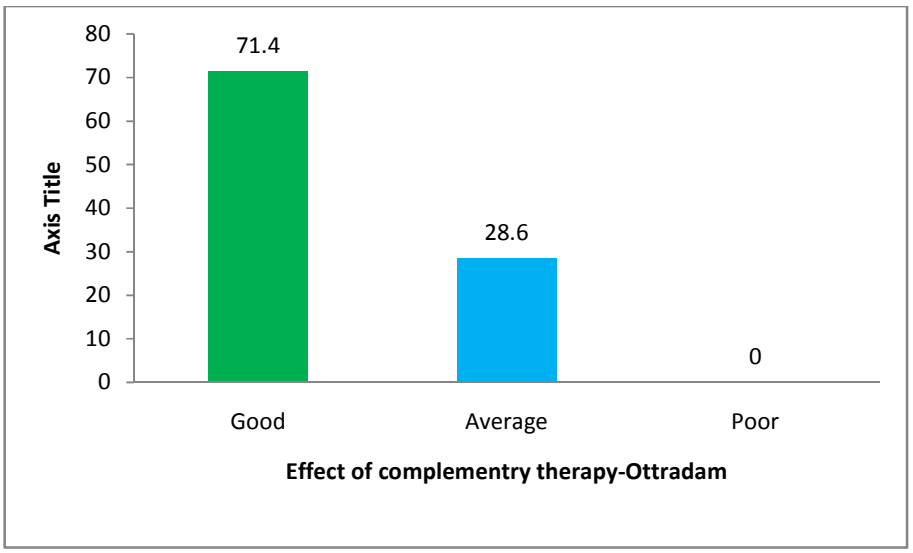



## Inference

Administration of trial drug along with complementary therapy (massage) had a good response 70% average with 20% and mild with 10%

**Table 22. Effect of therapy along with trail drug(Ottradm)**

| S.no | Effect of therapy | No. Of patients | Percentage(%) |
|---|---|---|---|
| 1 | Marked effect | 5 | 71.4 |
| 2 | Moderate effect | 2 | 28.6 |
| 3 | Mild effect | 0 | 0 |

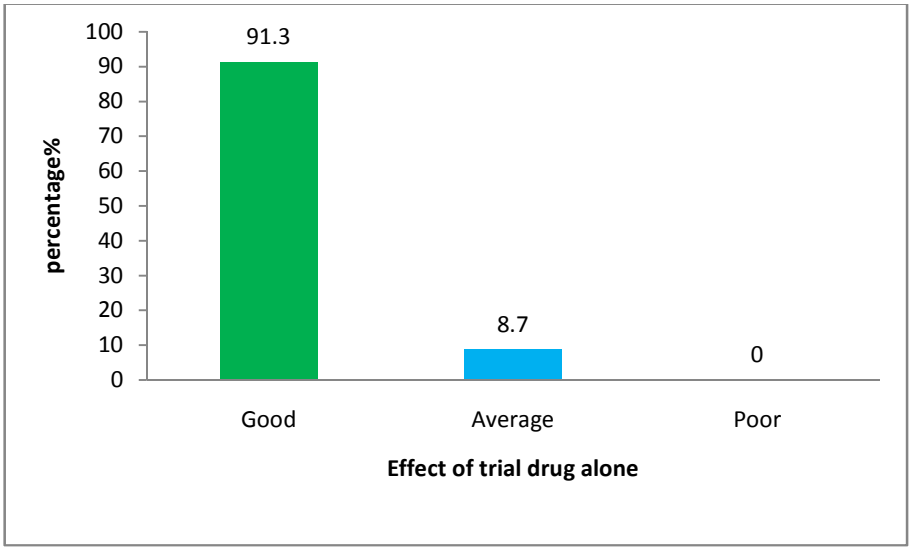



## Inference

Administration of trial drug along with complementary therapy (Ottradam) had a good response 71.4% average with 28.6%.

**Table 23. Effect of trail drug alone**

| S.no | Effect of therapy | No. Of patients | Percentage(%) |
|---|---|---|---|
| 1 | Good | 21 | 91.3 |
| 2 | Average | 2 | 8.7 |
| 3 | Poor | 0 | 0 |




**Inference**

Administration of trial drug alone had a good response 91.3% average with 8.7%.

# DISCUSSION

Kumba vatham is one among the 18 varaity of vatha diseass mentioned in yugi vaithiya chinthamani 800, kumbavatham clinical features resembles with periarthritis of shoulder in modern medicine. Twenty three op cases and 17 IP cases selected for treatment . The main clinical features of kumba vatham is pain in shoulder joint and upper limb, stiffness and restricted movement. Siddha method of diagnosis was carried out with the help of modern investigation in the diagnosis was carried out with the help of modern investigation in the diagnosis was confined and treatment with trail medicine is clearly observed.

The above said, quote from siddha literature predicts the fact that we should chose medicines for diseases and nor diseases for medicine. The trail drug was internal Santhira Pragasa Mathiraiand external sembai thylam.

**Incidene with age distribution:**

The dominant of the disease was found to be higher in the age group of 51 – 60 years (47.5%).

**Incidence with sex distribution:**

Among the 40 patient selection the dominant of the disease was found to be higher in females(67.5%)

**Incidence with reference to socio economic status:**

I this clinical study most of the patients belongs to middle socio economic status(70%)

**Disturbances in vatha**

Viyanan and Samanan was affected in all 40 cases (100%) abanan affected in 18 patients (45%).

**Disturbances in Pitha**

Sathagapitham was affected in all 40 cases (100%), ranjagam affected in 12.5% patients and anar pitham 7.5% patients

**Disturbances in Kabha**

Santhigam was affected in all 40 cases (100%).

**Thinai**

About 90% of patients from maruthanilam and remaining 10% from the neithal

**Seasonal distribution**

Most of the patients came during muthuvenir kalam 22.5% and remaining patients are came from Munpani kaalam 25% koothir kaalam 17.5%, Pinpani kaalam 12.5%, Elavenil kaalam7.5%.

**Occupational status**

The rate of incidence is higher in occupational group which includes home maker (35%) and farmer (32.5%), Tailors (12.5%), manual worker (12.5%). Homemakers are mostly affected.

**Clinical Manifestations**

Pain in the shoulder joint is present in all forty cases (100%), 64.7% of cases had radiating pain in upper limbs 100% of cases had restricted movement. Hence symptoms associated very well with the disease as proved by the statistical tests.

**Duration of illness**

Most of the patient with the disease Kumbavatham reflected its symptoms over a period of 6 - 12 months which was confirmed during the history taking while 40% of the patients reported the data.

**Udal Thathukkal**

In this study the patients was affected by Enbu, moolai 87.5%, Saaram affected in 7.5%, Oon affected in 7.5% cases.

**Envagai Envagai Thervugal**

In this study thontha naadi was noted in all 40 cases, malam was affected in 45% of cases

In naadi 67.5% were vatha pitha naadi, 30% were pitha vatha naadi and remaining were kabavathanaadi.

**Investigation**

Laboratory investigations were done in all the cases before and after treatment. The significant variation occur in parameters like ESR and HB, while other parameters have insignificant variation.

**Pre clinical studies**

The biochemical study of santhira pragasa mathirai had revealed the presence of sulphate, chloride, calcium, phosphate, unsaturated compound and amino acid

**Pharmacological studies**

The pharmacological studies done in Santhira Pragasa Mathirairevealed the presence of actions such as

- Anti – inflammatory action
- Analgesic activity.

**Toxicity studies**

Acute and subacute toxicity studies in rats for "Santhira Pragasa Mathirai" revealed that it has no toxicity effect.

**Treatment**

The treatment was aimed to retain the deranged thoshas and providing relief from symptoms. Before treatment the patients were advised to take vellai ennai 15ml with hot water during morning for first day of treatment.

From the second day onwards Internal medicine Santhira Pragasa Mathirai 130mgs two times a day after food and sembai thylam is given as external.

At the time of treatment the patients were advised to follow pathiyam and specifically advised to avoid foods which increase vadha.

Along with the course of treatment the complementary therapies like Thokkanam and Ottradam therapy were given additionally to some of the patients.

The outcome of this study is mainly assessed by reduction in pain in shoulder joint. Increased range of reduction of restricted movements and improvement in quality of life oxford pain assessment scale was also used to detect proper outcome. No adverse effect was noted for both internal and external medicine along with the course of treatment.

# SUMMARY

40 cases with Kumbavatham were diagnosed clinically based on yugi 800 and admitted in the inpatient ward and outpatient ward of post graduate department of sirappu maruthuvam, Government Siddha Medical College Hospital, palayamkottai and treated by the trial medicines.

- Laboratory diagnosis of Kumbavatham was done by siddha diagnostic principles and endorsed by modern methods of investigations.
- The various siddha aspects of examination of the disease were carried out and were recorded in the proforma.
- The trial medicine chosen for both internal and external treatments were Santhira Pragasa Mathirai130 mgs/days in BD sembai thylam (External) for forty days as per the severity of the diseases,
- Before starting the treatment careful detailed history was carried out and recorded for the forty selected cases.
- During the period of treatment all the patients were put under pathiyam (A specific dietary regimen)
- A periodical laboratory investigation was made for all the cases along with the radiological investigations.
- The observations made during the clinical study shows that the main internal drug for Santhira Pragasa Mathirai is clinically effective.
- Though there was appreciable clinical improvement, there were not much remarkable radiographic changes.
- The action of external application sembai thylam with Thokkanam and Ottradam is also quite remarkable.

# CONCLUSION

All 40 patients (23 OPD and 17 IP – 10 patients with trial medicines and Massage, 7 with ottradam along with trial medicines). were treated for this dissertation work with Santhira Pragasa Mathirai 130 mgs/day in BD and sembai thylam (externally)

In the pre clinical study pharmacological evaluation of the trial drug shows.

- Significant analgesic effect
- Significant Anti inflammatory effect (Internal medicine)

In the preclinical study toxicity study of "chanthra prakasa mathirai" shows that the trial drug had no acute toxicity.

The overall effect of the clinical trial drug are

| | | |
|---|---|---|
| good effect | - | 82.5% |
| Average effect | - | 15% |
| poor effect | - | 2.5% |

This result of the clinical trial illustrates the marked effect of the drugs and complementary therapy.

The trial drug Santhira Pragasa Mathirai and external sembai thylam is effective. No adverse effects were noticed during the treatment period. So the trial medicine is safe and easily preparable medicine.

**LIST OF OUT PATIENTS OF PG III SIRAPPU MARUTHUVAM DEPARTMENT GIVEN**

1.SANTHIRA PRAGASA MATHIRAI – INTERNAL 2. SEMBAI THYLAM – EXTERNAL

| S.no | Op.no | Name | Age/sex | Occupation | Date of admission | Date of discharge | Total no. of days treated | Results |
|---|---|---|---|---|---|---|---|---|
| 1 | 64725 | Thirumalai kumar | 41/M | Manual worker | 29.07.17 | 06.09.17 | 40 days | Good |
| 2 | 65233 | Balasubramaniyan | 34/M | Manual worker | 31.07.17 | 04.09.17 | 36 days | Good |
| 3 | 65635 | Subramaniyan | 60/M | Hotel worker | 02.08.17 | 10.09.17 | 40 days | Good |
| 4 | 65831 | Arumugam | 52/M | Farmer | 02.08.17 | 10.09.17 | 40 days | Good |
| 5 | 66491 | Prakash kumar | 42/M | Farmer | 04.08.17 | 12.09.17 | 40 days | Good |
| 6 | 67590 | najima | 38/F | House wife | 08.08.17 | 16.09.17 | 40 days | Good |
| 7 | 68051 | Fathima | 44/F | Tailor | 09.08.17 | 14.09.17 | 37 days | Average |
| 8 | 68986 | Seethayammal | 60/F | Manaual worker | 12.08.17 | 20.09.17 | 40 days | Good |
| 9 | 71494 | Marybakiyam | 58/F | House wife | 21.08.17 | 29.09.17 | 40 days | Good |
| 10 | 109709 | Jeya | 33/F | Tailor | 12.12.17 | 20.01.18 | 40 days | Good |
| 11 | 110284 | Seyathu alima | 40/F | Tailor | 13.12.17 | 19.01.18 | 38 days | Good |
| 12 | 112014 | Mariyammal | 45/F | Manaual worker | 19.12.17 | 27.01.18 | 40 days | Good |
| 13 | 113841 | Vanitha | 40/F | House wife | 25.12.17 | 02.02.18 | 40 days | Good |
| 14 | 6473 | Pattammmal | 58/F | House wife | 19.01.18 | 27.02.18 | 40 days | Good |
| 15 | 6474 | Muthulaxmi | 38/F | Tailor | 19.01.18 | 25.02.18 | 38 days | Average |
| **16** | 6475 | Bathma | 42/F | House wife | 19.01.18 | 27.02.18 | 40 days | Good |
| **17** | 7765 | Latchmi | 44/F | House wife | 23.01.18 | 03.03.18 | 40 days | Good |
| **18** | 13668 | Ramamoorthi | 60/M | Farmer | 09.02.18 | 19.03.18 | 39 days | Good |
| **19** | 16535 | Mariyammal | 52/F | Farmer | 17.02.18 | 29.03.18 | 40 days | Good |
| **20** | 17482 | Rajamani | 48/M | Farmer | 20.02.18 | 27.03.18 | 36 days | Good |
| **21** | 30642 | Seyath alif fathima | 34/F | House wife | 02.04.18 | 11.05.18 | 40 days | Good |
| **22** | 35323 | Kaleeswari | 38/F | Farmer | 18.04.18 | 27.05.18 | 40 days | Good |
| **23** | 35324 | rajeswaran | 52/M | Farmer | 18.04.18 | 27.05.18 | 40 days | Good |

**LIST OF IN PATIENTS OF PG III SIRAPPU MARUTHUVAM DEPARTMENT GIVEN**

1.SANTHIRA PRAGASA MATHIRAI – INTERNAL 2. SEMBAI THYLAM – EXTERNAL

| S.no | Ip.no | Name | Age/sex | Occupation | Date of admission | Date of discharge | Total no. of days treated | Results |
|---|---|---|---|---|---|---|---|---|
| **1** | 3226 | Bagavathi | 60/f | Farmer | 10.12.17 | 29.12.17 | 20 days | Good |
| **2** | 3237 | Mary | 60/f | Farmer | 11.12.17 | 02.01.18 | 23 days | Good |
| **3** | 3259 | Madasamy | 58/m | Farmer | 13.12.17 | 06.01.18 | 26 days | Good |
| **4** | 3283 | Ramaiah | 60/m | Farmer | 14.12.17 | 06.01.18 | 24 days | Average |
| **5** | 3303 | Rani | 49/f | Tailor | 18.12.17 | 06.01.18 | 20 days | Good |
| **6** | 03 | Lakshmi | 60/f | Housewife | 01.01.18 | 21.01.18 | 21 days | Good |
| **7** | 13 | Latha | 36/f | Housewife | 02.01.18 | 21.01.18 | 20 days | Good |
| **8** | 185 | RamaLakshmi | 35/f | Housewife | 25.01.18 | 23.02.18 | 30 days | Good |
| **9** | 324 | saraswathi | 60/f | Housewife | 08.02.18 | 23.02.18 | 16 days | Average |
| **10** | 370 | arumugam | 55/f | Farmer | 12.02.18 | 05.03.18 | 22 days | Good |
| **11** | 572 | issakiyammal | 35/f | Farmer | 02.03.18 | 17.03.18 | 16 days | Average |
| **12** | 576 | Nagammal | 60/f | Housewife | 03.03.18 | 17.03.18 | 15 days | Average |
| **13** | 900 | Maharaja | 48/m | Manual worker | 04.04.18 | 23.04.18 | 20 days | Good |
| **14** | 923 | Meenatchi | 55/f | Housewife | 05.04.18 | 24.04.18 | 20 days | Good |
| **15** | 933 | Pandaram | 60/m | Hotel worker | 06.04.18 | 15.04.18 | 10 days | Poor |
| **16** | 934 | Kaliyappan | 52/m | Hotel worker | 06.04.18 | 15.05.18 | 40 days | Good |
| **17** | 1142 | Devi | 37/f | Housewife | 26.04.18 | 04.06.18 | 40 Days | Good |

**INVESTICATION OF RANGE OF MOTION IN OUTPATIENTS**

| S.No | OP. No | FLEXON (IN DEGREES) | | EXTENSION | | ABDUCTION (IN DEGREES) | | AST-I.R | | AST-E.R | | RESULT |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | |
| 1 | 64725 | 70 | 180 | 25 | 30 | 60 | 180 | +ve | N | +ve | N | Good |
| 2 | 65233 | 60 | 160 | 20 | 25 | 55 | 150 | +ve | N | +ve | N | Good |
| 3 | 65635 | 120 | 180 | 20 | 30 | 65 | 160 | +ve | N | +ve | N | Good |
| 4 | 65831 | 60 | 180 | 15 | 30 | 75 | 180 | +ve | N | +ve | N | Good |
| 5 | 66491 | 150 | 180 | 20 | 35 | 45 | 180 | +ve | N | +ve | N | Good |
| 6 | 67590 | 90 | 180 | 15 | 25 | 70 | 180 | +ve | N | +ve | N | Good |
| 7 | 68051 | 80 | 150 | 10 | 20 | 50 | 145 | +ve | N | +ve | N | Average |
| 8 | 68986 | 110 | 160 | 25 | 35 | 60 | 180 | +ve | N | +ve | N | Good |
| 9 | 71494 | 60 | 140 | 10 | 25 | 65 | 160 | +ve | N | +ve | N | Good |
| 10 | 109709 | 150 | 180 | 25 | 40 | 110 | 170 | +ve | N | +ve | N | Good |
| 11 | 110284 | 150 | 140 | 25 | 30 | 70 | 140 | +ve | N | +ve | N | Good |
| 12 | 112014 | 90 | 180 | 20 | 40 | 75 | 180 | +ve | N | +ve | N | Good |
| 13 | 113841 | 70 | 160 | 25 | 35 | 110 | 170 | +ve | N | +ve | N | Good |
| 14 | 6473 | 100 | 180 | 20 | 35 | 120 | 180 | +ve | N | +ve | N | Good |
| 15 | 6474 | 40 | 110 | 10 | 15 | 60 | 90 | +ve | +ve | +ve | N | Average |
| 16 | 6475 | 120 | 180 | 15 | 45 | 120 | 180 | +ve | N | +ve | N | Good |
| 17 | 7765 | 80 | 180 | 20 | 35 | 90 | 180 | +ve | N | +ve | N | Good |
| 18 | 13668 | 45 | 110 | 10 | 20 | 35 | 100 | +ve | +ve | +ve | N | Good |
| 19 | 16535 | 100 | 180 | 25 | 45 | 100 | 175 | +ve | N | +ve | N | Good |
| 20 | 17482 | 80 | 180 | 20 | 45 | 100 | 170 | +ve | N | +ve | N | Good |

BT-Before Treatment AT – After Treatment AST- Apley's Scratch Test ER – External Rotation IR-Internal Rotation

**INVESTICATION OF RANGE OF MOTION IN IN-PATIENTS**

| S.No | IP. No | FLEXON (IN DEGREES) | | EXTENSION | | ABDUCTION (IN DEGREES) | | AST-I.R | | AST-E.R | | RESULT |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | |
| 1 | 30642 | 60 | 180 | 30 | 45 | 75 | 160 | +ve | N | +ve | N | Good |
| 2 | 35323 | 50 | 165 | 25 | 35 | 80 | 170 | +ve | N | +ve | N | Good |
| 3 | 35324 | 70 | 170 | 15 | 40 | 110 | 180 | +ve | N | +ve | N | Good |
| 4 | 3226 | 80 | 110 | 25 | 30 | 75 | 145 | +ve | N | +ve | N | Good |
| 5 | 3237 | 55 | 145 | 20 | 25 | 70 | 155 | +ve | N | +ve | N | Good |
| 6 | 3259 | 60 | 180 | 15 | 35 | 45 | 160 | +ve | N | +ve | N | Good |
| 7 | 3283 | 70 | 165 | 15 | 25 | | | +ve | N | +ve | N | Average |
| 8 | 3303 | 100 | 180 | 20 | 45 | 70 | 180 | +ve | N | +ve | N | Good |
| 9 | 3 | 60 | 155 | 20 | 25 | 60 | 135 | +ve | N | +ve | N | Good |
| 10 | 13 | 45 | 180 | 15 | 40 | 75 | 165 | +ve | N | +ve | N | Good |
| 11 | 185 | 70 | 180 | 25 | 45 | 50 | 160 | +ve | N | +ve | N | Good |
| 12 | 324 | 40 | 125 | 10 | 15 | 45 | 100 | +ve | N | +ve | N | Average |
| 13 | 370 | 55 | 135 | 10 | 25 | 50 | 145 | +ve | N | +ve | N | Good |
| 14 | 572 | 65 | 140 | 15 | 30 | 55 | 135 | +ve | N | +ve | N | Average |
| 15 | 576 | 45 | 110 | 10 | 20 | 45 | 110 | +ve | N | +ve | N | Average |
| 16 | 900 | 70 | 180 | 10 | 40 | 100 | 180 | +ve | N | +ve | N | Good |
| 17 | 923 | 60 | 165 | 15 | 35 | 90 | 175 | +ve | N | +ve | N | Good |
| 18 | 933 | 70 | 110 | 15 | 20 | 45 | 100 | +ve | +ve | +ve | +ve | Poor |
| 19 | 934 | 90 | 170 | 30 | 45 | 110 | 180 | +ve | N | +ve | N | Good |
| 20 | 1142 | 100 | 180 | 20 | 45 | 60 | 180 | +ve | N | +ve | N | Good |

BT-Before Treatment AT – After Treatment AST- Apley's Scratch Test ER – External Rotation IR-Internal Rotation

# BLOOD INVESTICATION BEFORE AND AFTER TREATMENT – OP PATIENT

| S.NO | OP.NO | TC | | DC | | | | | | | | | | HB | | ESR | | BLOOD SUGAR | | | | BLOOD UREA | | SERUM CHOLESTEROL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | N | | L | | E | | B | | M | | | | | | F | | PP | | | | | |
| | | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT |
| **1** | 64725 | 7400 | 7500 | 72 | 72 | 25 | 26 | 3 | 2 | 0 | 0 | 0 | 0 | 11.0 | 12 | 12 | 12 | 92 | 100 | 136 | 141 | 29 | 28 | 190 | 192 |
| **2** | 65233 | 7900 | 8400 | 64 | 62 | 34 | 36 | 2 | 2 | 0 | 0 | 0 | 0 | 12.4 | 13 | 11 | 10 | 148 | 151 | 193 | 194 | 32 | 32 | 158 | 157 |
| **3** | 65635 | 7500 | 7900 | 65 | 66 | 33 | 34 | 2 | 2 | 0 | 0 | 0 | 0 | 13.7 | 13.9 | 16 | 13 | 115 | 115 | 164 | 170 | 25 | 24 | 210 | 211 |
| **4** | 65831 | 9200 | 9300 | 67 | 67 | 30 | 31 | 3 | 2 | 0 | 0 | 0 | 0 | 8.7 | 9.6 | 18 | 14 | 92 | 109 | 124 | 125 | 27 | 26 | 160 | 165 |
| **5** | 66491 | 8800 | 8900 | 62 | 63 | 34 | 34 | 4 | 3 | 0 | 0 | 0 | 0 | 14 | 14.5 | 9 | 10 | 84 | 106 | 137 | 134 | 40 | 35 | 154 | 155 |
| **6** | 67590 | 8200 | 8300 | 60 | 61 | 38 | 37 | 2 | 2 | 0 | 0 | 0 | 0 | 13.5 | 13.6 | 17 | 17 | 172 | 170 | 240 | 247 | 35 | 34 | 170 | 179 |
| **7** | 68051 | 7500 | 7800 | 67 | 67 | 32 | 31 | 1 | 2 | 0 | 0 | 0 | 0 | 10.4 | 11.3 | 13 | 10 | 155 | 151 | 270 | 265 | 31 | 32 | 112 | 110 |
| **8** | 68986 | 8200 | 8900 | 66 | 66 | 32 | 33 | 2 | 1 | 0 | 0 | 0 | 0 | 9.5 | 9.7 | 10 | 8 | 96 | 97 | 126 | 120 | 34 | 33 | 212 | 200 |
| **9** | 71494 | 7800 | 7600 | 62 | 64 | 33 | 34 | 5 | 2 | 0 | 0 | 0 | 0 | 11.7 | 13.6 | 26 | 20 | 170 | 167 | 290 | 277 | 28 | 32 | 160 | 169 |
| **10** | 109709 | 8500 | 8200 | 67 | 63 | 27 | 35 | 6 | 2 | 0 | 0 | 0 | 0 | 10.6 | 11.5 | 18 | 15 | 84 | 101 | 222 | 121 | 39 | 35 | 216 | 201 |
| **11** | 110284 | 7600 | 8300 | 59 | 62 | 31 | 33 | 10 | 5 | 0 | 0 | 0 | 0 | 9.2 | 9.5 | 20 | 25 | 153 | 150 | 175 | 186 | 37 | 36 | 190 | 195 |
| **12** | 112014 | 7000 | 7700 | 64 | 64 | 28 | 30 | 8 | 6 | 0 | 0 | 0 | 0 | 13.1 | 12.9 | 22 | 26 | 114 | 116 | 190 | 180 | 30 | 33 | 226 | 227 |
| **13** | 113841 | 8800 | 8900 | 64 | 64 | 29 | 33 | 7 | 3 | 0 | 0 | 0 | 0 | 12.8 | 13.1 | 19 | 15 | 142 | 147 | 210 | 205 | 33 | 29 | 190 | 195 |
| **14** | 6473 | 7600 | 8300 | 65 | 67 | 28 | 29 | 7 | 4 | 0 | 0 | 0 | 0 | 10.6 | 11.7 | 8 | 12 | 103 | 117 | 145 | 151 | 29 | 25 | 195 | 190 |
| **15** | 6474 | 7500 | 8300 | 70 | 70 | 27 | 26 | 3 | 4 | 0 | 0 | 0 | 0 | 10.5 | 10.9 | 24 | 19 | 86 | 97 | 121 | 131 | 28 | 28 | 218 | 217 |
| **16** | 6475 | 9200 | 9200 | 67 | 66 | 28 | 31 | 5 | 3 | 0 | 0 | 0 | 0 | 11.2 | 12.8 | 21 | 13 | 135 | 145 | 164 | 162 | 26 | 27 | 160 | 163 |
| **17** | 7765 | 7600 | 8100 | 69 | 64 | 28 | 33 | 3 | 3 | 0 | 0 | 0 | 0 | 11.6 | 13.4 | 16 | 12 | 98 | 112 | 120 | 122 | 35 | 34 | 196 | 172 |
| **18** | 13668 | 8800 | 9100 | 59 | 66 | 32 | 30 | 9 | 4 | 0 | 0 | 0 | 0 | 8.4 | 8.3 | 22 | 13 | 93 | 99 | 114 | 120 | 37 | 37 | 182 | 180 |
| **19** | 16535 | 8000 | 7900 | 69 | 68 | 26 | 30 | 5 | 2 | 0 | 0 | 0 | 0 | 12.2 | 14.5 | 21 | 15 | 135 | 135 | 175 | 170 | 39 | 35 | 175 | 177 |
| **20** | 17482 | 6900 | 7100 | 66 | 67 | 31 | 31 | 3 | 2 | 0 | 0 | 0 | 0 | 11.4 | 13.6 | 12 | 11 | 145 | 142 | 255 | 250 | 37 | 33 | 187 | 189 |
| **21** | 30642 | 7200 | 7900 | 58 | 63 | 37 | 34 | 5 | 3 | 0 | 0 | 0 | 0 | 12.5 | 12.7 | 14 | 15 | 105 | 117 | 155 | 155 | 35 | 37 | 169 | 167 |
| **22** | 35323 | 8800 | 9100 | 63 | 69 | 36 | 30 | 1 | 1 | 0 | 0 | 0 | 0 | 11.5 | 12.5 | 18 | 13 | 120 | 118 | 147 | 149 | 38 | 35 | 192 | 189 |
| **23** | 35324 | 6800 | 7100 | 67 | 68 | 30 | 30 | 3 | 2 | 0 | 0 | 0 | 0 | 13.5 | 14.7 | 13 | 14 | 80 | 85 | 162 | 171 | 25 | 27 | 214 | 211 |

# BLOOD INVESTICATION BEFORE AND AFTER TREATMENT – IP PATIENT

| S.NO | IP.NO | DC | | | | | | | | | | HB | | ESR | | BLOOD SUGAR | | | | BLOOD UREA | | SERUM CHOLESTEROL | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Tc | | N | | L | | E | | M | | | | | | F | | PP | | | | | |
| | | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT | BT | AT |
| 1 | 3226 | 9200 | 9100 | 61 | 63 | 35 | 34 | 4 | 3 | 0 | 0 | 14.5 | 14.5 | 15 | 13 | 155 | 161 | 220 | 221 | 35 | 36 | 200 | 201 |
| 2 | 3237 | 8700 | 8300 | 70 | 69 | 28 | 29 | 2 | 2 | 0 | 0 | 10.5 | 11.2 | 17 | 16 | 85 | 89 | 142 | 145 | 40 | 39 | 175 | 179 |
| 3 | 3259 | 8300 | 8400 | 59 | 61 | 31 | 35 | 10 | 4 | 0 | 0 | 9.5 | 9.5 | 9 | 11 | 103 | 103 | 151 | 149 | 27 | 25 | 163 | 161 |
| 4 | 3283 | 7900 | 7800 | 69 | 67 | 27 | 29 | 4 | 4 | 0 | 0 | 15.5 | 15.7 | 11 | 13 | 135 | 137 | 257 | 253 | 32 | 31 | 179 | 173 |
| 5 | 3303 | 8100 | 7900 | 63 | 64 | 30 | 33 | 7 | 3 | 0 | 0 | 13.5 | 14 | 13 | 12 | 110 | 111 | 157 | 156 | 34 | 35 | 185 | 182 |
| 6 | 03 | 7700 | 7700 | 67 | 63 | 29 | 35 | 4 | 2 | 0 | 0 | 10.5 | 11.5 | 19 | 17 | 145 | 149 | 260 | 265 | 33 | 33 | 189 | 184 |
| 7 | 13 | 6900 | 7100 | 62 | 63 | 29 | 30 | 9 | 7 | 0 | 0 | 14.2 | 14.5 | 21 | 20 | 115 | 117 | 147 | 149 | 28 | 29 | 193 | 191 |
| 8 | 185 | 9200 | 9300 | 66 | 65 | 30 | 31 | 4 | 4 | 0 | 0 | 15.2 | 14.5 | 24 | 21 | 85 | 93 | 152 | 157 | 31 | 30 | 200 | 203 |
| 9 | 324 | 8600 | 8700 | 67 | 64 | 31 | 33 | 2 | 3 | 0 | 0 | 10.5 | 11.5 | 19 | 16 | 138 | 135 | 230 | 229 | 32 | 31 | 219 | 214 |
| 10 | 370 | 9300 | 9100 | 63 | 67 | 32 | 30 | 5 | 3 | 0 | 0 | 13.5 | 12.5 | 23 | 21 | 90 | 89 | 143 | 141 | 39 | 37 | 167 | 169 |
| 11 | 572 | 9700 | 9600 | 65 | 62 | 29 | 31 | 6 | 4 | 0 | 0 | 11.5 | 12.7 | 27 | 25 | 141 | 139 | 243 | 247 | 36 | 39 | 173 | 171 |
| 12 | 576 | 7300 | 7100 | 61 | 64 | 33 | 32 | 6 | 4 | 0 | 0 | 13.5 | 14.5 | 22 | 20 | 151 | 149 | 281 | 289 | 33 | 32 | 164 | 162 |
| 13 | 900 | 6900 | 7000 | 58 | 65 | 39 | 32 | 3 | 3 | 0 | 0 | 16.5 | 16.7 | 19 | 17 | 147 | 146 | 262 | 254 | 36 | 32 | 186 | 184 |
| 14 | 923 | 7100 | 7300 | 63 | 62 | 31 | 34 | 6 | 4 | 0 | 0 | 13.5 | 13.8 | 9 | 8 | 128 | 131 | 231 | 227 | 39 | 40 | 197 | 193 |
| 15 | 933 | 6300 | 6900 | 64 | 63 | 33 | 34 | 3 | 3 | 0 | 0 | 11.9 | 12 | 11 | 9 | 136 | 136 | 222 | 226 | 28 | 27 | 164 | 166 |
| 16 | 934 | 6700 | 6800 | 67 | 67 | 29 | 31 | 4 | 2 | 0 | 0 | 13.5 | 14 | 8 | 8 | 89 | 90 | 160 | 157 | 31 | 33 | 179 | 173 |
| 17 | 1142 | 9100 | 9300 | 69 | 68 | 25 | 29 | 6 | 3 | 0 | 0 | 12.5 | 12.8 | 7 | 11 | 93 | 91 | 165 | 159 | 29 | 31 | 205 | 201 |

## URINE EXAMINATION BEFORE & AFTER TREATMENT – OUT PATIENTS

| S.no | OP.NO | Before treatment | | | After treatment | | |
|---|---|---|---|---|---|---|---|
| | | Albumin | Sugar | Deposit | Albumin | Sugar | Deposit |
| 1 | 64725 | NIL | NIL | NAD | NIL | NIL | NAD |
| 2 | 65233 | NIL | + | NAD | NIL | NIL | NAD |
| 3 | 65635 | NIL | NIL | NAD | NIL | NIL | NAD |
| 4 | 65831 | NIL | NIL | NAD | NIL | NIL | NAD |
| 5 | 66491 | Trace | NIL | 1-3 pus cells | NIL | NIL | NAD |
| 6 | 67590 | NIL | ++ | NAD | NIL | ++ | NAD |
| 7 | 68051 | NIL | ++ | NAD | NIL | ++ | NAD |
| 8 | 68986 | NIL | NIL | NAD | NIL | NIL | NAD |
| 9 | 71494 | NIL | ++ | NAD | NIL | ++ | NAD |
| 10 | 109709 | Trace | NIL | 1-2 pus cells | NIL | NIL | NAD |
| 11 | 110284 | NIL | + | NAD | NIL | + | NAD |
| 12 | 112014 | Trace | NIL | 1 – 2 pus cells | NIL | NIL | NAD |
| 13 | 113841 | NIL | + | NAD | NIL | + | NAD |
| 14 | 6473 | NIL | NIL | NAD | NIL | NIL | NAD |
| 15 | 6474 | NIL | NIL | NAD | NIL | NIL | NAD |
| 16 | 6475 | NIL | + | NAD | NIL | + | NAD |
| 17 | 7765 | NIL | NIL | NAD | NIL | NIL | NAD |
| 18 | 13668 | NIL | NIL | NAD | NIL | NIL | NAD |
| 19 | 16535 | NIL | + | NAD | NIL | + | NAD |
| 20 | 17482 | NIL | ++ | NAD | NIL | ++ | NAD |
| 21 | 30642 | NIL | NIL | NAD | NIL | NIL | NAD |
| 22 | 35323 | Trace | NIL | 1 – 3 pus cells | NIL | NIL | NAD |
| 23 | 35324 | NIL | NIL | NAD | NIL | NIL | NAD |

## URINE EXAMINATION BEFORE & AFTER TREATMENT – IN PATIENTS

| S.no | Ip.no | Before treatment | | | After treatment | | |
|---|---|---|---|---|---|---|---|
| | | Albumin | Sugar | Deposit | Albumin | Sugar | Deposit |
| 1 | 3226 | Nil | ++ | NAD | Nil | ++ | NAD |
| 2 | 3237 | Trace | Nil | 1 -2 pus cells | Nil | Nil | NAD |
| 3 | 3259 | Nil | Nil | NAD | Nil | ++ | NAD |
| 4 | 3283 | Nil | ++ | NAD | Nil | Nil | NAD |
| 5 | 3303 | Nil | Nil | NAD | Nil | Nil | NAD |
| 6 | 03 | Nil | ++ | NAD | Nil | ++ | NAD |
| 7 | 13 | Nil | Nil | NAD | Nil | Nil | NAD |
| 8 | 185 | Nil | Nil | NAD | Nil | Nil | NAD |
| 9 | 324 | Nil | + | NAD | Nil | + | NAD |
| 10 | 370 | Nil | Nil | NAD | Nil | Nil | NAD |
| 11 | 572 | Nil | ++ | NAD | Nil | ++ | NAD |
| 12 | 576 | Nil | + | NAD | Nil | + | NAD |
| 13 | 900 | Nil | ++ | NAD | Nil | ++ | NAD |
| 14 | 923 | Nil | + | NAD | Nil | + | NAD |
| 15 | 933 | Nil | + | NAD | Nil | + | NAD |
| 16 | 934 | Trace | Nil | 1 – 3 puscells | Nil | Nil | NAD |
| 17 | 1142 | Nil | Nil | NAD | Nil | Nil | NAD |

## INGREDIENTS OF SANTHIRA PRAGASA MATHIRAI (INTERNAL)

நாபி

மிளகு

இஞ்சி

வெங்காரம்

## INGREDIENTS OF SEMBAI THYLAM (EXTERNAL)

கருஞ்செம்பை

நல்லெண்ணெய்

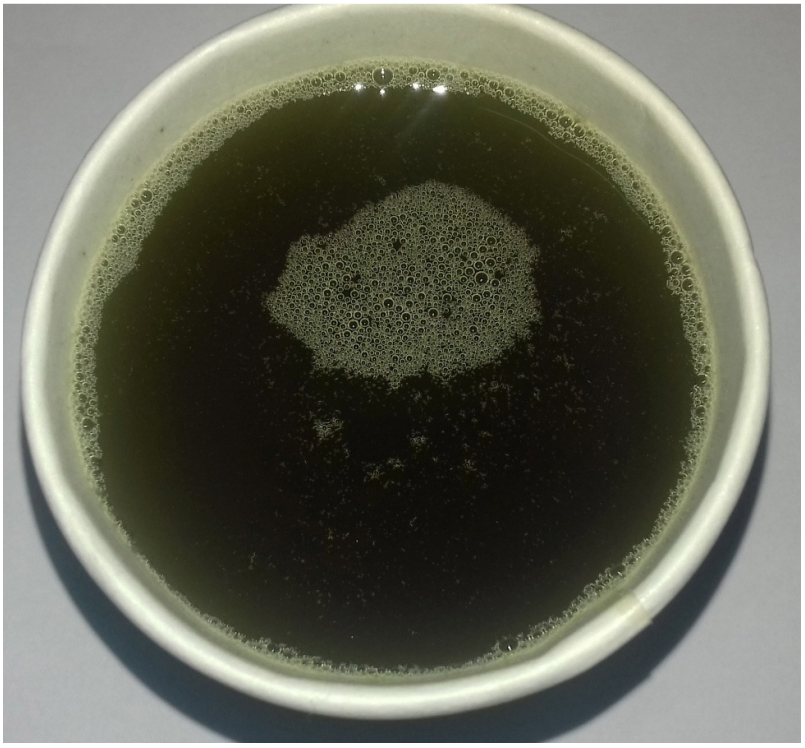
பளிங்கு சாம்பிராணி

டீக்காமல்லி

வெள்ளுள்ளி

## SANTHIRA PRAGASA MATHIRAI

## SEMBAI THYLAM



## ANNEXURE - I

## PROPERTIES OF TRIAL DRUGS

### INTERNAL MEDICINE

#### 1. வெங்காரம்

| | | |
|---|---|---|
| Chemical Name | : | BORAX |
| வேறுபெயர்கள் | : | பொரிகாரம், காரம், உருக்கினம், உருக்கு மித்திரன், டங்கணம், தூமத்தையடக்கி |
| சுவை | : | இனிப்புடன் கூடிய துவர்ப்புச்சுவை உடையது. |
| வீரியம் | : | வெப்பம் |
| செய்கை | : | குளிர்ச்சியுண்டாக்கி, சிறுநீர்பெருக்கி, ருதுஉண்டாக்கி, பிரசவகாரி, கற்கரைச்சி |

**பொதுகுணம்**

"சொறிபுடையெண் குன்மறமை சோரி யாசம்
பறிகிரகணி கல்லூணம் பன்னோய் - நெறியைத்
தடங்கணங்க பங்கிருமி சர்ப்பவிடஞ் சந்நி
யிடங்கணங்க லக்கிற்போ மெண்"

வெங்காரத்தினால், தவளைச்சொறி, புடை, எண்வகைக் குன்மம், தினவு, இரத்தமூலம், ஒழக்குக்கிரகணி, அஸ்மரி, பங்குவாதம், பல்நோய் மூத்திரகிரிச்சரங்கள் கபாதிக்கம், புழு, பாம்பு முதலியவைகளால் உண்டாகும் நஞ்சு, சந்நிபாதம் முதலிய நோய்கள் நீங்கும்.

#### 2. மிளகு

| | | |
|---|---|---|
| Botanical Name | : | PIPERNIGRUM |
| Family | : | Piperaceae |
| வேறுபெயர்கள் சருமபந்தம், | : | கலினை, களி, காயம், கோளகம், திரங்கல், மிரியல், வள்ளிசம், மாசம், குறுமிளகு, மலையாளி |
| சுவை | : | கைப்பு, கார்ப்பு |
| தன்மை | : | வெப்பம் |
| பிரிவு | : | கார்ப்பு |
| வளர்இயல்பு | : | கொடி |
| செய்கை | : | காறலுண்டாக்கி, அகட்டுவாய்வகற்றி, முறைவெப்பகற்றி, தடிப்புண்டாக்கி, வெப்பமுண்டாக்கி, வாதமடக்கி, வீக்கங்கரைச்சி. |

**பொதுகுணம்**

"அளவையுறாக்காரம் அடைந்திருக்கும் வாத
விளைவையெல் லாமறுக்கும் மெய்யே – மிளகின்காய்
கண்டவர்க்கும் இன்பமாம் காரிகையே! சீழ்மூலங்
கொண்டவர்க்கு நன்மருந்தாங் கூறு."

- **அகத்தியர் குணவாகடம்**

இதனால் குளிர்சுரம், பாண்டு, கோழை, கழிச்சல், குன்மம், வாயு, சுவையின்மை, வெறி, மூலம், சன்னியாசம், அபஸ்மாரம், பிரமேகம், இருமல், பக்கவாதம், குய்யரோகம், சோணிதவாதம், களநோய், செவிவலி, இரத்தகுன்மம், செரியாமை, காமாலை இவை போகும்.

**Chemical constituents**

Alkaloids - Piperine (or) Pipirine, Piperidine, Balsamic volatile essential oil chavicin, starch, lignin, gum, fat.

**3. நாபி**

| | | |
|---|---|---|
| Botanical Name | : | ACONTIUM NAPELLUS |
| Family | : | Ranunculaceae |
| வேறுபெயர்கள் | : | நாபிநாபம், வசநாபி, வத்சநாபி, விடம், மருதம். |
| சுவை | : | கைப்பு |
| தன்மை | : | வெப்பம் |
| பிரிவு | : | கார்ப்பு |
| வளர்இயல்பு | : | செடி |
| செய்கை | : | வியர்வைப்பெருக்கி, சிறுநீர்ப்பெருக்கி, முறைவெப்பகற்றி, துயரடக்கி,தாபகமற்றி, வெப்படக்கி, மூர்ச்சையுண்டாக்கி, தாதுவெப்பகற்றி |

**பொதுகுணம்**

"வாதவலி மந்தமறல் மாறாக் கபப்பிணிகள்
ஓதுகுட்டு குன்மந்தேள் ஓடுங்காண் - காதலர்தம்
புத்தியோ டாருயிரும் பூவும் வளைகுழலே!
சுத்திசெய்த நாவியின்பேர் சொல்"

- அகத்தியர் குணவாகடம்

இது கீழ்வாக்கடுப்பு, செரியாமை, ஐயப்பிணிகள், பெருநோய், குன்மம், தேள்நஞ்சு ஆகியவற்றை போக்கும்.

**Chemical constituents :**

Aconitine, Picroaconine, aconine, benzyl aconine, homonapelline.

### 4. இஞ்சி

| | | |
|---|---|---|
| Botanical Name | : | ZINGIBER OFFICINALE |
| Family | : | Zingiberaceae |
| வேறுபெயர்கள் | : | அல்லம், ஆர்த்தரகம், ஆத்திரகம், இலாக்கொட்டை, நறுமறுப்புமதில். |
| சுவை | : | கார்ப்பு |
| தன்மை | : | வெப்பம் |
| பிரிவு | : | கார்ப்பு |
| வளர்இயல்பு | : | தரைகீழ்தண்டு |
| செய்கை | : | அகட்டுவாய்வகற்றி, பசீத்தீத்தூண்டி, உமிழ்நீர்ப்பெருக்கி, செரிப்புண்டாக்கி, வெப்பமுண்டாக்கி, தடிப்புண்டாக்கி |

**பொதுகுணம்**

"இஞ்சிக் கிழங்குக் கிருமல்ஐயம் ஒக்காளம்
வஞ்சிக்குஞ் சன்னிசுரம் வன்பேதி – விஞ்சுகின்ற
சூலையறும் வாதம்போந் தூண்டாத தீபனமாம்
வேலையுறுங் கண்ணாய் - விளம்பு

இஞ்சியினால் இருமல், ஈளை, வெள்ளோக்காளம், அழல்குற்றம், வளிசூலை, முக்குற்ற நோய்கள், கோழைக்கூட்டம், செரியாக்கழிச்சல் இவைபோம். பசியுண்டாகும்.

**Chemical constituents**

Aromatic volatile oil, camphene, Phellandrone, Zingiberine, cineol and borneol, K-oxalate.

**EXTERNAL MEDICINE**

### 1. கருஞ்செம்பை

| | | |
|---|---|---|
| Botanical Name | : | SESBANIA AEGYPTICA |
| Family | : | Fabaceae |
| சுவை | : | கைப்பு, துவர்ப்பு |
| தன்மை | : | வெப்பம் |
| பிரிவு | : | கார்ப்பு |
| செய்கை | : | வெப்பமுண்டாக்கி, ருதுவுண்டாக்கி, துவர்ப்பி, புழக்கொல்லி, சிறுநீர்பெருக்கி, வீக்கங்கரைச்சி |

**பொதுகுணம்**

"விப்புருதிப் புண்ணாறும் வீறுகரப் பானும்போந்

தப்பாமல் மேகந் தணியுங்காண் - வெப்பார்

கபரோக மேகுஞ் கருஞ்செம்பை யொன்றுக்

கிபமா முலைமாதே! எண்"

கருஞ்செம்பை இலையால், வெள்ளை, புண், கட்டி, கரப்பான், ஐயம், தீக்குற்றங்கள் ஆகிய இவைகள் போகும்.

**Chemical constituents**

| | | |
|---|---|---|
| Seeds contains: fat | - | 4.8 PC |
| Albumin oils | - | 33.7 PC |
| Carbohydrate | - | 18.2 PC |
| Cellulose | - | 28.3 PC |
| Ash | - | 4.2 PC |

**2. வெள்ளுள்ளி**

| | | |
|---|---|---|
| Botanical Name | : | ALLIUM SATIVUM |
| Family | : | Liliaceae |
| வேறுபெயர்கள் | : | வெள்ளைபூண்டு, இலசுனம், பூண்டு, காயம் |
| சுவை | : | கார்ப்பு |
| தன்மை | : | வெப்பம் |
| பிரிவு | : | பூண்டு |
| வளர்இயல்பு | : | உரமாக்கி, உடற்றேற்றி, வெப்பமுண்டாக்கி |

**பொதுகுணம்**

சன்னியொடு வாதந் தலைநோவு தாள்வலி

மன்னிவரு நீர்க்கோவை வன்சீதம் - அன்னமே!

உள்ளுள்ளி கண்பாய் உளைமூல ரோகமும் போம்

வெள்ளுள்ளி தன்னால் வெருண்டு

சிறிய கட்டிகள், செவிடு, நாட்பட்ட இருமல், இரைப்பு, வயிற்றுப்புழு, முப்பிணி, வளிநோய்கள், ஐயத்தலைவலி, வாய்நோய், நீரேற்றம், சீதக்கழிச்சல், மூலம் தீரும்.

**Chemical constituents**

- Diallyl disulfide
- Diallyl trisulfide
- Allicin
- Vinyldithins
- Ajoene

### 3. நல்லெண்ணெய்

| | | |
|---|---|---|
| Botanical Name | : | Sesamum Indicum |
| Family | : | Pedaliaceae |
| வேறுபெயர்கள் | : | திலம், எள்நெய் |
| சுவை | : | இனிப்பு |
| தன்மை | : | வெப்பம் |
| பிரிவு | : | இனிப்பு |

**பொதுகுணம்**

புத்திநயனக்குளிர்ச்சி பூரிப்பு மெய்ப்புளகஞ்
சத்துவங் கந்தி தனியிளமை – மெத்தவுண்டாங்
கண்ணோய் செவிநோய் கபாலவழல் காசநோய்
புண்ணோய்போ மெண்ணெய்யாற் போற்றும்.

புத்திக்குத் தெளிவு, விழிகளுக்குக் குளிர்ச்சி, உடல்பூரிப்பு, உடல்வன்மை ஆகியவற்றைத் தருவதோடு, கண்ணோய், காதுநோய், தலைக்கொதிப்பு, சொறி, சிரங்கு, புண் முதலியவைகளையும் போக்கும்.

**Chemical constituents**

- Palmitic acid
- Stearic acid
- Archidic acid
- Linoleic acid
- Oleic acid

### 4. பளிங்கு சாம்பிராணி

| | | |
|---|---|---|
| Botanical Name | : | STYRAX BENZOIN |
| Family | : | Styraceae |
| வேறுபெயர்கள் | : | பெண் குமைஞ்சான், தூபம், மலாக்காச் சாம்பிராணி |
| சுவை | : | கார்ப்பு |
| தன்மை | : | வெப்பம் |
| பிரிவு | : | கார்ப்பு |
| வளர்இயல்பு | : | செடி |
| செய்கை | : | வெப்பமுண்டாக்கி, கோழையகற்றி, தடிப்புண்டாக்கி, சிறுநீர்ப்பெருக்கி |

**பொதுகுணம்**

"வாதசீ தங்கண்ணோய் மாறாத் தலைவலியும்
ஓதமுறு பீனசமும் ஒட்டுங்காண் - பூதலத்தில்
வேம்பிதுதான் என்ன மிகுகசப்பை வாய்க்களிக்கும்
சாம்பிராணி என்னும் சரக்கு"

இதனால் வளி, ஐயநோய்கள், கண்ணோய், நீங்காத்தலைநோய், நீர்ப்பீனசம் விலகும்.

**Chemical constituents**

- Benzoic acid
- Cinnamic acid
- Vanillin
- Volatile oil

**5.டீக்காமல்லி**

| | | |
|---|---|---|
| Botanical Name | : | Gardenia Gummifera |
| Family | : | Rubiaceae |
| Part used | : | Resin |

**Chemical constituents**

It contains 89.9% resins,
0.1% volatile oils
Besides these it contains certain
Alkaloids and minerals

## ANNEXURES -II

## QUALITATIVE AND QUANTITATIVE ANALYSIS

## BIO-CHEMICAL ANALYSIS OF SANTHIRA PRAGASA MATHIRAI (IN POWDER FORM)

**Preparation of the extract:**

5gms of the drug was weighed accurately and placed in a 250ml clean beaker. Then 50ml of distilled water is added and dissolved well. Then it is boiled well for about 10 minutes. It is cooled and filtered in a 100ml volumetric flask and then it is made to 100ml with distilled water. This fluid is taken for analysis.

### QUALITATIVE ANALYSIS

| S.NO | EXPERIMENT | OBSERVATION | INFERENCE |
|---|---|---|---|
| 1. | **TEST FOR CALCIUM**<br>2ml of the above prepared extract is taken in a clean test tube. To this add 2ml of 4% Ammonium oxalate solution | No white precipitate is formed | Absence of calcium |
| 2. | **TEST FOR SULPHATE**<br>2ml of the extract is added to 5% Barium chloride solution. | A white precipitate is formed | **Indicates the presence of sulphate** |
| 3. | **TEST FOR CHLORIDE**<br>The extract is treated with silver nitrate solution | A white precipitate is formed | **Indicates the presence of chloride** |
| 4. | **TEST FOR CARBONATE**<br>The substance is treated with concentrated HCL. | No Brisk effervescence is formed | Absence of carbonate |
| 5. | **TEST FOR STARCH**<br>The extract is added with weak iodine solution | No Blue colour is formed | Absence of starch |
| 6. | **TEST FOR FERRIC IRON**<br>The extract is acidified with Glacial acetic acid and potassium ferro cyanide. | No blue colour is formed | Absence of ferric iron. |
| 7. | **TEST OF FERROUS IRON**<br>The extract is treated with concentrated Nitric acid and Ammonium thio cyanide | No Blood red colour is formed | Absence of ferrous iron. |

| | | | |
|---|---|---|---|
| | solution. | | |
| 8. | **TEST FOR PHOSPHATE**<br>The extract is treated with Ammonium Molybdate and concentrated nitric acid | Yellow precipitate is formed | **Indicates the presence of phosphate** |
| 9. | **TEST FOR ALBUMIN**<br>The extract is treated with Esbach's reagent | No Yellow precipitate is formed | Absence of Albumin. |
| 10. | **TEST FOR TANNIC ACID**<br>The extract is treated with ferric chloride. | No Blue black precipitate is formed | Absence of tannic acid. |
| 11. | **TEST FOR UNSATURATION**<br>Potassium permanganate solution is added to the extract | It gets decolourised. | **Indicates the presence of unsaturated compound.** |
| 12. | **TEST FOR THE REDUCING SUGAR**<br>5ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 mts and add 8-10 drops of the extract and again boil it for 2 minutes. | No colour change occurs | Absence of reducing sugar. |
| 13. | **TEST FOR AMINO ACID**<br>One or two drops of the extract is placed on a filter paper and dried well. After drying, 1% Ninhydrin is sprayed over the same and dried it well. | Violet colour is formed. | **Indicates the presence of Amino acid.** |
| 14. | **TEST FOR ZINC**<br>The extract is treated with Potassium Ferrocyanide. | No white precipitate is formed | Absence of Zinc. |

**Inference:**

The given sample of "SANTHIRA PRAGASA MATHIRAI" contains Sulphate, Chloride, Phosphate, Unsaturated compound, Reducing sugar, Amino acid.

## PHARMACOLOGICAL ANALYSIS

### EFFECT OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM ON ACETIC ACID INDUCED WRITHING IN MICE[1]

1. Kaneria MS, Naik SR, Kohli RK. Anti-inflammatory,antiarthritic and analgesic activity of a herbal formulation. Indian J.Experimental Biol. 2007; 45: 279.

Acetic acid induced writhing method was adopted for evaluation of analgesic activity. Writhing is defined as a stretch, tension to one side, extension of hind legs, contraction of the abdomen so that the abdomen of mice touches the floor, turning of trunk (twist). Any writhing is considered as a positive response.

### MATERIAL AND METHODS

### ANIMALS:

Healthy Swiss albino rats of either sex weighing 20-25g were used in this study. All the animals were obtained from Animal house of the KMCH College of Pharmacy, Coimbatore. The animals were housed comfortably in a group of six in a single clean plastic cage with a metal frame lid on its top. They were housed under standard environmental conditions of temperature (24±1°C) and relative humidity of 30-70 %. A 12:12 h light dark cycle was followed. All animals had free access to water and standard pelletized laboratory animal diet ad libitum. All the experimental procedures and protocols used in this study were reviewed and approved via the Approval No. ---------- by the Institutional Animal Ethical Committee (IAEC) of KMCH College of Pharmacy, Coimbatore (685/PO/Re/S/2002/CPSCEA Dated 21st August 2002 constituted in accordance with the guidelines of the CPCSEA, Government of India.

### DRUGS:

Acetic acid (Sigma Chemical Co. Bangalore, India) and Indomethacin were purchased from (Ranbaxy, India). All drugs were dissolved in saline. The different doses of **SANTHIRA PRAGASA MATHIRAI** were prepared **CHUKKU KASAYAM**.The control group received vehicle as control. All drugs were prepared just before use.

**PREPARATION OF ACETIC ACID:**

A solution of acetic acid (1% v/v) in distilled water was prepared.

**CONVERSION FORMULA**:

Human dose is 130 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 30 gm of Mice

130 mg x 2(a) x 0.018 (b) = 2.34 (c) /30 gm of Mice

2.34/1000x30 = 0.070 mg /kg

Experimental Doses Calculated as per the standard procedures are

| S.No | Groups | Dose /kg, weight | Volume of administration |
|---|---|---|---|
| 1 | Vehicle Control | -- | 1 ml |
| 2 | Therapeutic Dose | 0.070 mg /kg | 1 ml |
| 3 | Middle Dose | 0.351mg/kg | 1 ml |
| 4 | High Dose | 1.755mg/kg | 1 ml |

**EXPERIMENTAL PROCEUDRE:**

GROUP 1 – CONTROL (IP injection of 0.1 ml 1% acetic acid)

GROUP 2 -- IP injection of 0.1 ml 1% acetic acid + Indomethacin (5mg/kg, i.p)

GROUP 3 -- 0.1 ml 1% acetic acid (ip) + **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** 0.070 mg /kg **(po)**

GROUP 4 -- 0.1 ml 1% acetic acid (ip) + **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** 0.351mg/kg **(Po)**

GROUP 5 -- 0.1 ml 1% acetic acid (ip) + **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** 1.755mg/kg **(po)**

**PROCEDURE:**

Wister albino mice of either sex were divided into five different groups each containing Six animals, the animals were marked individually. Food was withdrawn 12 hours prior to drug administration till completion of experiment. The animals were weighed and numbered appropriately. The test and standard drugs were given orally. After 60 minutes writhing was induced by intra-peritoneal injection of 1% acetic acid in volume of 0.1 ml/10g body weight. The writhing episodes were recorded for 30 minutes; stretching movements consisting of arching of the back, elongation of body and extension of hind limbs were counted.

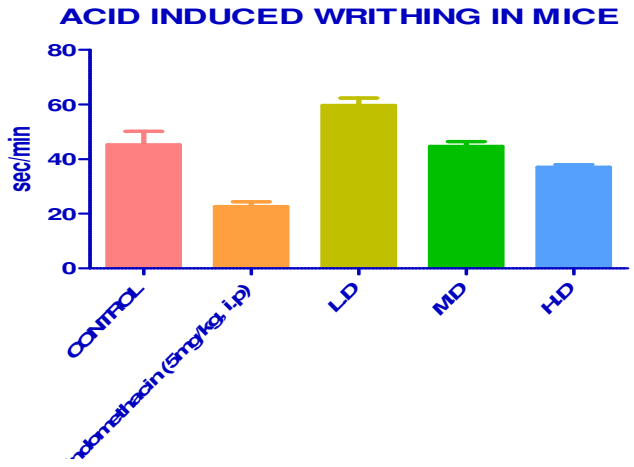
Anti-nociceptive activity was expressed as the percentage inhibition of abdominal constrictions using the ratio:

(Control mean – Treated mean) × 100/Control mean

**EFFECT OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM ON ACETIC ACID INDUCED WRITHING IN MICE[1]**

| GROUP | No of Writhing (30min) | Inhibition (%) |
|---|---|---|
| **CONTROL** | 45.33±4.807 | --- |
| **Indomethacin (5mg/kg, i.p)** | 22.67±1.764** | 49.98 % |
| **S M 0.028mg/kg(po)** | 59.67±2.728* | 31.63 % |
| **S M 0.014mg/kg(po)** | 37.67±2.963$^{ns}$ | 16.85 % |
| **S M 0.28mg/kg(po)** | 32.67±3.333$^{ns}$ | 27.92 % |

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



## EFFECT OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAMON HOT PLATE METHOD IN MICE[1]

1. Turner RA. Screening methods in pharmacology. In: Turner, R., Hebborn, P. (eds.). Academic press, New York. 1965; 100.

The paws of mice and rats are very sensitive to heat at temperatures which are not damaging the skin. The responses are jumping, withdrawal of the paws and licking of the paws.

### MATERIAL AND METHODS

### ANIMALS:

Healthy Swiss albino rats of either sex weighing 20-25g were used in this study. All the animals were obtained from Animal house of the KMCH College of Pharmacy, Coimbatore. The animals were housed comfortably in a group of six in a single clean plastic cage with a metal frame lid on its top. They were housed under standard environmental conditions of temperature (24±1°C) and relative humidity of 30-70 %. A 12:12 h light dark cycle was followed. All animals had free access to water and standard pelletized laboratory animal diet ad libitum. All the experimental procedures and protocols used in this study were reviewed and approved via the Approval No. ---------- by the Institutional Animal Ethical Committee (IAEC) of KMCH College of Pharmacy, Coimbatore (685/PO/Re/S/2002/CPSCEA Dated 21st August 2002 constituted in accordance with the guidelines of the CPCSEA, Government of India.

The hot plate, which is commercially available, consists of a electrically heated surface. The temperature is controlled for 55° to 56 °C. This can be a copper plate or a heated glass surface. The animals are placed on the hot plate and the time until either licking or jumping occurs is recorded by a stop-watch.

**EXPERIMENTAL PROCEUDRE:**

**GROUP 1 – CONTROL**

**GROUP 2 – Pentazocine (10mg/kg, I.P)**

**GROUP 3 --** SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM **0.54 mg /kg(po)**

**GROUP 4 –** SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM **2.7mg/kg(po)**

**GROUP 5 --** SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM **13.5mg/kg(po)**

**PROCEUDRE:**

Mice were screened by placing them on a hot plate maintained at 55±1ºC and recording the reaction time in seconds for forepaw licking or jumping. Only mice which reacted within 15sec and which did not show large variation when tested on four separate occasions, each 15min apart, were taken for the test. The time for forepaw licking or jumping on the heated plate of the analgesiometer maintains at 55ºC was taken as the reaction time. Prior to treatment, the reaction time of each mouse (licking of the forepaws or jumping response) was done at 0- and 10-min interval. The average of the two readings was obtained as the initial reaction time (*Tb*). The reaction time (*Ta*) following the administration of the ----------, Pentazocine and distilled water was measured at 0.5, 1, 2, and 3h after latency period of 30min.

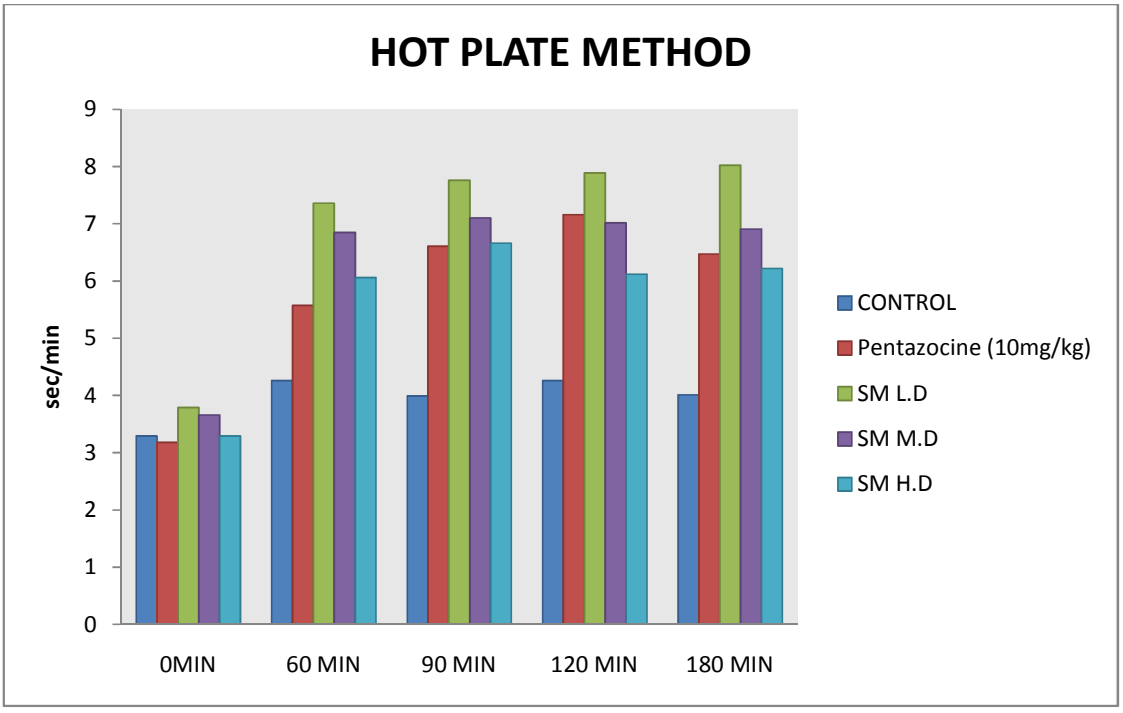
The following calculation was:

Percentage analgesic activity = $Ta\text{-}Tb/Tb \times 100$

**EFFECT OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAMBY HOT PLATE METHOD IN MICE:-**

| GROUP | Reaction time in seconds at time (minutes) (mean ± sem) (mean ± sem) | | | | |
|---|---|---|---|---|---|
| | O mints | 60 mints | 90 mints | 120 mints | 180 mints |
| CONTROL | 3.297±0.1584 | 3.187±0.1683 | 3.79±0.3027 | 3.663±0.1641 | 3.29±0.06028 |
| STANDARD | 4.26±0.03215 | 5.57±0.421* | 7.36±0.2691*** | 6.85±0.2836** | 6.063±0.1419** |
| S M + LOW DOSE | 3.993±0.4619 | 6.613±0.07623*** | 7.767±0.3184*** | 7.107±0.1272*** | 6.663±0.178*** |
| S M + MIDDLE DOSE | 4.263±0.3283 | 7.16±0.3523** | 7.89±0.3557*** | 7.027±0.3555*** | 6.217±0.1725** |
| S M + HIGH DOSE | 4.01±0.125 | 6.473±0.2972** | 8.02±0.1159 | 6.913±0.2885* | 6.22±0.4917** |

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's $^{***}P< 0.001$, $^{**}P < 0.01$, $^{*}P < 0.05$ calculated by comparing treated group with CONTROL group.



## EFFECT OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM ON CARRAGEENAN-INDUCED LOCALISED INFLAMMATORY PAIN IN RATS


### SUMMARY

The study plan was developed based on the guidelines of Vogel[1] and also it has reference to Chao Ma and Jun-Ming Zhang[2] and Walker et al. [3,] Winter CA, Risley EA, Nuss GW. Carrageenin induced edema in hind paw of the rat as an assay for anti-inflammatory drugs. Proc Soc Exp Biol Med. 1962;111:544–7.

### OBJECTIVE

To study the anti-inflammatory effect of **SANTHIRA PRAGASA MATHIRAI** were prepared **WITH CHUKKU KASAYAM** in the rat model of Carrageenan-induced localized inflammation.

### Methods:

**Test System**

| | | |
|---|---|---|
| Species | : | Rat |
| Strain | : | Albino Wister |
| Age | : | 6-8 weeks at the time of dosing |
| Total no. of Rats | : | 24 |
| Sex | : | Male |
| Weight | : | 150 gm |

The animals were housed in polypropylene cages with stainless steel top grills having facilities for holding pellet food and drinking water in bottle with stainless steel sipper tube. Each cage contained 6 rats. All rats had free access to potable water and standard pelleted laboratory animal diet *ad libitum*. Paddy husk was used as bedding material. The animals were divided into 5 groups (6 rats/group). Localized inflammatory pain was induced in all groups of animals by intraplantar injection of carrageenan (50 µl of 3% suspension).

One day before the experiment, three basal readings of hind paw in each rat were recorded. Group 1 received vehicle orally, Group 2 received a standard drug Diclofenac sodium (10 mg/kg i.p), whereas groups 3,4and 5 received **SANTHIRA PRAGASA MATHIRAI**. The doses of **SANTHIRA PRAGASA MATHIRAI** were prepared **WITH CHUKKU KASAYAM**, whereas Diclofenac sodium was dissolved in normal saline. After 30 min, the rats were challenged with subcutaneous injection of 0.1 ml of 1% w/v solution of carrageenan into the sub plantar region of left paw. The paw was marked with ink at the level of lateral malleolus and immersed in mercury up to the mark. The paw volume was measured at 0, 1, 2, 3, 4, 5 and $6^{th}$ hr after carrageenin injection using Digital Plethysmometer. The difference between initial and subsequent reading gave the actual edema volume.

**CONVERSION FORMULA**:

Human dose is 130 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 150 gm of Rat

130 mg x 2(a) x 0.018 (b) = 2.34 (c) /150 gm of Rat

2.34/1000x150 = 0.351 mg /kg

Experimental Doses Calculated as per the standard procedures are

| S.No | Groups | Dose /kg, weight | Volume of administration |
|---|---|---|---|
| 1 | Vehicle Control | CHUKKU KASAYAM | 1 ml |
| 2 | Therapeutic Dose | 0.351 mg /kg | 1 ml |
| 3 | Middle Dose | 1.755mg/kg | 1 ml |
| 4 | High Dose | 8.775mg/kg | 1 ml |

**EXPERIMENTAL DESIGN:**

**Group-I:** Served as a negative control (0.1ml of 1% carrageenin)

**Group-II:** Served as standard received Diclofenac sodium (10mg/kg, i.p) +

(0.1ml of 1% carrageenin)

**Group-III:** Received **SANTHIRA PRAGASA MATHIRAI** were prepared **with** CHUKKU KASAYAM

(0.351 mg /kg) + (0.1ml of 1% carrageenin)

**Group IV:** Received **SANTHIRA PRAGASA MATHIRAI** were prepared **with** CHUKKU KASAYAM

(1.755mg/kg) + (0.1ml of 1% carrageenin)

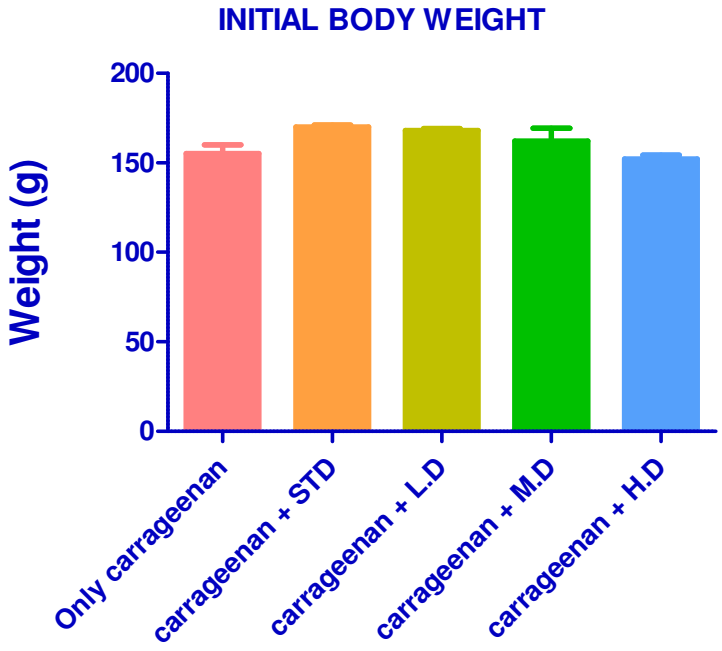
**Group V:** Received **SANTHIRA PRAGASA MATHIRAI** were prepared **with** CHUKKU KASAYAM

(8.775mg/kg) + (0.1ml of 1% carrageenin)

**TABLE: EFFECT OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM ON Carrageenin -INDUCED PAW EDEMA IN RATS (BODY WEIGHT in gms)**

| Group | Control | carrageenan + Standard | carrageenan + LD | carrageenan + M D | carrageenan + H D |
|---|---|---|---|---|---|
| INITIAL BODY WEIGHT | 155.3±4.807 | 170±1.155 | 168±1.155 | 162±7.211 | 152±2.309 |

Values are expressed as the mean ± S.D. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. ns- not significant $^{**}P< 0.05$ calculated by comparing treated group with control group.



**EFFECT OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM ON Carrageenin -INDUCED PAW EDEMA IN RATS**

| Group | Mean paw volume before carrageenan injection | Paw Volume after induction with carrageenin Increase in paw volume (ml) after carrageenan injection (mean ± SEM)/Percent inhibition of edema | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 0 min | 30 min | 1h | 2h | 3h | 4h | 5h | 6h |
| **Control** | 4.15± 0.2211 | 7.383± 0.2176 | 7.353± 0.08647 | 8.537 ± 0.122 | 8.333 ± 0.1189 | 7.87± 0.1124 | 8.203± 0.4072 | 7.923± 0.3217 |
| **Standard** | 4.19± 0.1739 | 7.007±0.1444 | 7.773± 0.2764 | 7.923 ± 0.2973 | 8.057 ± 0.2603 | 7.907± 0.05364 | 6.183± 0.0636 | 5.81± 0.3308 |
| carrageenan + LD | 3.55± 0.2994 | 6.867±0.2338 | 7.51± 0.1097 | 8.007 ± .1981 | 8.073 ± 0.1737 | 7.58± 0.3014 | 6.76± 0.5107 | 6.14± 0.4158 |
| carrageenan + M D | 4.303±0.1302 | 7.117±0.1241 | 7.71±0.02309 | 7.677 ± 0.1317 | 8.137 ± 0.1471 | 7.787± 0.01202 | 6.36± 0.1286 | 5.667± 0.06642 |
| carrageenan + H D | 4.293± 0.2959 | 7.367± 0.2896 | 7.587± 0.1622 | 7.803 ± 0.4965 | 7.82± 0.3223 | 7.2± 0.1644 | 6.97± 0.07506 | 6.21± 0.2857 |

Values are expressed as the mean ± S.D. Statistical significance (p) calculated by one way ANOVA followed by dunnett's. ns- not significant $^{**}P< 0.05$ calculated by comparing treated group with control group.

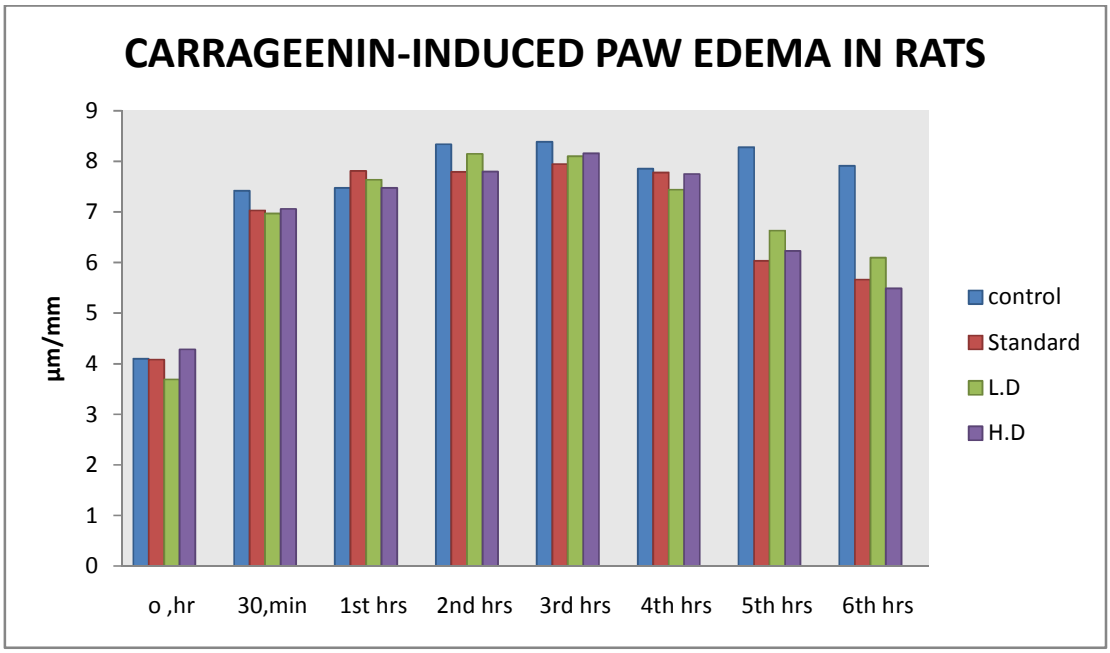

CARRAGEENIN-INDUCED PAW EDEMA IN RATS
µm/mm
9
8
7
6
5
4
3
2
1
0
o ,hr
30,min
1st hrs
2nd hrs
3rd hrs
4th hrs
5th hrs
6th hrs
control
Standard
L.D
H.D

**TABLE: EFFECT OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM ON Carrageenin -INDUCED PAW EDEMA IN RATS**

ONLY CARRAGEENIN

CARRAGEENIN+ STD

CARRAGEENIN+ L.D

CARRAGEENIN+ M.D

CARRAGEENIN+ H D

**ACUTE TOXICITY STUDY IN FEMALE WISTER RATS TO EVALUATE TOXICITY PROFILE OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM**

**Table 1. Test substance details**

| | |
|---|---|
| Name of the test substance | **SANTHIRA PRAGASA MATHIRAI** |
| Colour of the test substance | BROWN |
| Nature of the test substance | Powder |

**Table 2. Experimental protocol**

| | |
|---|---|
| Name of the study | Acute toxicity |
| Guideline followed | OECD 423 method-acute toxic class method |
| Animals | Healthy young adult female wister rats, nulliparous, non-pregnant |
| Body weight | 150-200 g |
| Sex | female |
| Administration of dose and volume | 2000 mg/kg in 200g body weight, single dose in 1 ml |
| Number of groups and animals | 5 groups and 3 animals in each group 100mg,250mg,500mg,1000mgand 2000mg/kg |
| Route of administration | Oral Cavage (po) |
| Vehicle | **CHUKKU KASAYAM** |

**Table3. Housing and feeding conditions**

| | |
|---|---|
| Room temperature | 22°C ± 3°C |
| Humidity | 40-60% |
| Light | 12 h : 12h (light : dark cycle) |
| Feed | Standard laboratory animal food pellets with water *ad libitum* |

**Table 4. Study period and observation parameters**

| | |
|---|---|
| Initial once observation | First 30 minutes and periodically 24 h |
| Special attention | First 1-4 h after drug administration |
| Long term observation | Upto 14 days |
| Direct observation parameters | Tremors, convulsions, salivation, diarrhea, lethargy, sleep and coma. |
| Additional observation parameters | Skin and fur, eyes and mucous membrane, respiratory, circulatory, autonomic and central nervous systems, somato motor activity and behavior pattern etc. |

The time of death, if any, is recorded. (Complete observations: annexure I). After administration of the drug, food is withheld for a further 1-2 hours.

**Study procedure**

Acute oral toxicity was performed as per organization for economic co-operation for development (OECD) guideline 423 method. The **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** was administered in a single dose by tuberculin syringe. Animals are fasted 3 h prior to dosing (food was withheld for 3 h but not water). Following the period of fasting animals was weighed and test substance was administered orally at a dose of 100mg,250mg,500mg,1000mgand 2000mg/kg. After the **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** administration, food was withheld 2 h in mice. Animals are observed individually after at least once during the first 30 minutes, periodically during the first 24 hrs, with special attention given during the first 4 hrs, and daily thereafter, for a total of 14 days.

**REPORT**

**Toxicological evaluation of SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM**

Table:5 Effect of **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** on acute toxicity test in female rats.

| S.N | Response | Head | | Body | | Tail | |
|---|---|---|---|---|---|---|---|
| | | **Before** | **After** | **Before** | **After** | **Before** | **After** |
| 1 | Alertness | Normal | Normal | Normal | Normal | Normal | Normal |
| 2 | Grooming | Absent | Absent | Absent | Absent | Absent | Absent |
| 3 | Touch response | Absent | Absent | Absent | Absent | Absent | Absent |
| 4 | Torch response | Normal | Normal | Normal | Normal | Normal | Normal |
| 5 | Pain response | Normal | Normal | Normal | Normal | Normal | Normal |
| 6 | Tremors | Absent | Absent | Absent | Absent | Absent | Absent |
| 7 | Convulsion | Absent | Absent | Absent | Absent | Absent | Absent |
| 8 | Righting reflux | Normal | Normal | Normal | Normal | Normal | Normal |
| 9 | Gripping strength | Normal | Normal | Normal | Normal | Normal | Normal |
| 10 | Pinna reflux | Present | Present | Present | Present | Present | Present |
| 11 | Corneal reflux | Present | Present | Present | Present | Present | Present |
| 12 | Writhing | Absent | Absent | Absent | Absent | Absent | Absent |
| 13 | Pupils | Normal | Normal | Normal | Normal | Normal | Normal |
| 14 | Urination | Normal | Normal | Normal | Normal | Normal | Normal |
| 15 | Salivation | Normal | Normal | Normal | Normal | Normal | Normal |
| 16 | Skin colour | Normal | Normal | Normal | Normal | Normal | Normal |
| 17 | Lacrimation | Normal | Normal | Normal | Normal | Normal | Normal |

**RESULT:**

From acute toxicity study it was observed that the administration of **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** to Female Wister rats did not induce drug-related toxicity and mortality in the animals up to 2000mg/kg in 200g female Wister rats. So No-Observed-Adverse-Effect- Level

(NOAEL) of **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** is 2000 mg/kg equal to human dose

**DISCUSSION**

**SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** was administered single time at the doses of 100mg, 250mg, 500mg, 1000mg and 2000mg/kg to female Wister rats and observed for consecutive 14 days after administration. Doses were selected based on the pilot study and literature review. All animals were observed daily once for any abnormal clinical signs. Weekly body weight and food consumption were recorded. No mortality was observed during the entire period of the study. Data obtained in this study indicated no significance physical and behavioral signs of any toxicity due to administration of **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** at the doses of 100 mg, 250mg ,500mg, 1000mg and 2000mg/kg to female Wister rats

At the 14th day, all animals were observed for functional and behavioral examination. In functional and behavioral examination, home cage activity, hand held activity were observed. Home cage activities like Body position, Respiration, Clonic involuntary movement, Tonic involuntary movement, Palpebral closure, Approach response, Touch response, Pinna reflex, Sound responses, Tail pinch response were observed. Handheld activities like Reactivity, Handling, Palpebral closure, Lacrimation, Salivation, Piloercetion, Papillary reflex, abdominal tone, Limb tone were observed. Functional and behavioral examination was normal in all treated groups. Food consumption of all treated animals was found normal as compared to normal group.

## SUMMARY & CONCLUSION:

**Summary:**

The present study was conducted to know single dose toxicity of **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** on female Wister rats. The study was conducted using 15 female Wister rats. The female animals were selected for study of 8- 12 weeks old with weight range of within ± 20 % of mean body weight at the time of randomization. The groups were numbered as group I, II, III, IV and V and dose with 100mg, 250mg, 500mg, 1000mg and 2000mg/kg of **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM**. The drug was

administered by oral route single time and observed for 14 days. Daily the animals were observed for clinical signs and mortality.

There were no physical and behavioral changes observed in Female Wister rats during 14 days. Mortality was not observed in any treatment groups.

**Conclusion:**

The study shows that **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** did not produce any toxic effect at dose of 100mg, 250mg, 500mg, 1000mg and 2000mg/kg to rats. So No-Observed-Adverse-Effect-Level (NOAEL) of **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** is 2000 mg/kg.

## 7.0 ABBREVIATIONS

| | |
|---|---|
| No. | Number |
| Mg | Milligram |
| Kg | Kilogram |
| $LD_{50}$ | Lethal Dose $_{50}$ |
| p.o | peros |
| ML | Milliliter |
| % | percentage |
| R&D | Research and Development |
| g% | Gram percentage |
| g | Gram |
| NOAEL | No-Observed-Adverse-Effect-Level |
| MLD | Minimum Lethal Dose |
| MTD | Maximum Tolerated Dose |
| OECD | Organisation of Economic Co-operation and Development |
| CPCSEA | Committee for the Purpose of Control and Supervision of Experiments on Animals |

## 8.0 REFERENCES:

1. OECD. Guideline for Testing of Chemicals 423, Acute oral toxicity (acute toxic class method). December 2001.

# SUB-ACUTE TOXICITY STUDY IN WISTER RATS TO EVALUATE TOXICITY PROFILE OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM

## Objective

The objective of this study is to evaluate the toxic effects, if any, as a result of the repeated once daily oral administration of **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** to Wister Albino rats for a minimum period of 28 consecutive days. This study will provide information on any major toxic effects, target organs and a rationale for concluding the No-Observed-Adverse-Effect-Level (NOAEL) and/or No Observed Effect Level (NOEL) / LOEL (Low Observed Effect Level) and risk assessment in humans.

## *1.* Test Guidelines

This study plan is prepared as per the following guidelines:

Schedule – Y, Amendment version 2005, Drugs and Cosmetics Rules, 1945.

OECD – 407 – Repeated dose 28-day Oral Toxicity Study in Rodents, Adopted 3 October, 2008.

### 1.1. Test System Details

| | | |
|---|---|---|
| Species | : | Rat |
| Strain | : | Wister Albino |
| Source | : | Sree Venkateshwara Enterprises Pvt Ltd, Bangalore |
| Age | : | 6-8 weeks |
| Sex | : | Male / Female (nulliparous and non-pregnant) |
| Body weight | : | 160.0to 180.0 g |

### 1.2. Acclimatization

Animals will be allowed to acclimatize to the experimental room conditions for five days prior to the commencement of dosing. During the acclimatization period, the animals will be observed daily for any apparent adverse clinical signs. Prior to assignment to the study and commencement of treatment, a detailed physical health examination will be performed on all animals by a

veterinarian and animals with any evidence of ill health or poor physical condition will not selected for the study.

### 1.3. Randomization and Grouping

On the starting day of dosing, the animals will be weighed and health examination will be performed by veterinarian. Animals will be randomly allocated to different groups according to their body weight by using MS-Excel sheet as described in the randomization SOP. Animals will be divided into four groups (vehicle control, low, intermediate, and high dose). At the initiation of the treatment, the body weight variation between the groups did not exceed ±20% of the mean weight of each sex.

### 1.4. Animal Identification

In each cage, animals will be identified with numbers by marking at the base of the ear. The cages will be identified with an attached colored cage label showing study number, study code, group number, sex, dose, strain, species, cage number, route of administration and animal number.

## *2.* Animal Husbandry

### 2.1. Animal Welfare and approval

The study was approved by the IAEC (SLS) and Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA registration number: Abc14).Their recommendations regarding animal care and handling will be followed.

### 2.2. Environmental Conditions

The temperature of the experimental room will be maintained at $22\pm3^0$C and the relative humidity between 30-70 %. The photoperiod will be 12 hours light and 12 hours dark cycles

### 2.3. Housing Conditions

Two animals will be housed in autoclaved polypropylene rat cages (Size in mm=L x W x H: 430 x 290 x 160) using paddy husk as the bedding material. Each cage will be fitted with a top grill having provision for keeping rodent pellet feed and an autoclaved polypropylene water bottle with stainless steel

drinking nozzle. Cages will be placed on 3-tier racks and cage rotation will be performed every week. Cages will be changed at least twice a week. The cages and water bottles will be cleaned and autoclave sterilized.

### 2.4. Sanitation

Each day, the floor of the animal room will be swept and mopped. Cages and bedding material will be changed once in three days and water bottles will be changed daily. All the experimental procedures will be done in a clean environment.

### 2.5. Feed

The experimental animals will be provided with irradiated rodent pellet feed *ad libitum* supplied from Sai feeds Pvt ltd, Chennai . Feed will be withheld for four hours prior to blood collection and necropsy.

### 2.6. Drinking Water

Animals will be provided with filtered drinking water *ad libitum* passed through water filter system (Aquaguard™) in autoclaved polypropylene bottles. Water bottles will be changed daily. Microbial analysis of water will be carried out once monthly and the report is maintained in the study file.

## *3.* Personnel Safety

All personnel handling animals undergo regular medical examination. Protective clothing like apron, face mask, head cap, and gloves will be used to maintain hygienic conditions.

## *4.* Materials and Methods

### 4.1. Preparation of Dose formulation

The dose formulation will be prepared under aseptic conditions as per SLS, SOP.

### 4.2. Route of Administration and Justification

Administration will be by oral gavage, as it is one of the possible routes of exposure.

### 4.3. Frequency and Duration of Administration

Once daily for 28 consecutive days

### 4.4. Dosing Procedure

The test item will be administered in once daily by oral gavage using a suitable intubation cannula fitted with a graduated syringe. The scheme of dosing and sacrifice time points are presented in the below below Table.

### 4.5. Experimental Procedures

All experimental procedures will be performed in accordance with the Study plan and Standard Operating Procedures (SOPs) of SLS.

**CONVERSION FORMULA**:

Human dose is 130 mg /kg day

Total clinical dose (a) x conversion factor (b) 0.018 = (c) per 150 gm of Rat

130 mg x 2(a) x 0.018 (b) = 2.34 (c) /150 gm of Rat

2.34/1000x150 = 0.351 mg /kg

Experimental Doses Calculated as per the standard procedures are

| S.No | Groups | Dose /kg, weight | Volume of administration |
|---|---|---|---|
| 1 | Vehicle Control | CHUKKU KASAYAM | 1 ml |
| 2 | Therapeutic Dose | 0.351 mg /kg | 1 ml |
| 3 | Middle Dose | 1.755mg/kg | 1 ml |
| 4 | High Dose | 8.775mg/kg | 1 ml |

### 1.1.1 Experimental Design

| Group No. | Group | Dose (mg/kg b.wt /day) | No. of Animals | |
|---|---|---|---|---|
| | | | Male | Female |
| G1 | Vehicle control | CHUKKU KASAYAM | 5 | 5 |
| G2 | Low dose of **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** | 0.351 mg /kg | 5 | 5 |
| G3 | Intermediate dose **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** | 1.755mg/kg | 5 | 5 |
| G4 | High dose **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** | 8.775mg/kg | 5 | 5 |

**Observations**

Animals will be observed daily throughout the treatment period at regular intervals. During the treatment period, animals will be observed twice daily for any clinical signs of toxicity, morbidity and mortality. All the surviving animals will be sacrificed at the end of scheduled period and subjected to gross necropsy and histopathological evaluations.

**Clinical Signs**

All the animals will be subjected to cage-side (home-cage) observations twice a day for any clinical signs of toxicity, preferably at the same time each day and considering the peak period of anticipated effect. In addition to home cage observations, a detailed clinical examination will be performed once prior to dosing and weekly thereafter during treatment period.

**Morbidity/ Mortality**

All animals will be examined twice a day for mortality and signs of morbidity.

**Body Weights**

Body weights will be recorded at the beginning of acclimatization, before randomization, there after at weekly intervals and at the time of necropsy.

**Feed Consumption**

Feed consumption will be calculated on a weekly basis throughout the study period.

**Hematology and Clinical Biochemistry**

Hematology and clinical biochemistry tests will be performed with terminally collected blood samples on day-29 from all animals. Animals will be deprived of feed overnight and blood samples will be collected by tapping the ear for visibility of the vein site and inserted the needle into the marginal ear vein and collected the blood into micro centrifuge tube. Approximately 0.5 ml of blood will be collected in vials containing 1% EDTA (20µl) as an anticoagulant for hematological analysis.

Approximately 2 ml blood will be collected from each animal in micro centrifuge tubes containing 15µl of heparin (19 units) and the plasma will be separated by centrifugation at 4000 rpm for ten minutes at $4^{o}$C. The plasma will be stored at -20 $^{o}$C ± 2 and used for all clinical chemistry analysis.

**Hematology**

Erythrocyte count (RBC), Total Leucocyte count (WBC), Hemoglobin (Hb), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC) and Platelet (PLTC).

**Clinical Biochemistry**

Glucose, Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Alkaline phosphatase (ALP), Total protein, Albumin, Creatinine, Urea, Cholesterol, Triglycerides, Sodium, Potassium, Calcium, and Chloride.

**Pathology**

All animals will be euthanized by $CO_2$ asphyxiation and subjected to necropsy under the supervision of the veterinary pathologist. Different tissues/organs of thoracic, abdominal and cranial cavities will be examined for any gross pathological changes. Tissues from vehicle control and high dose groups will be subjected to detailed histopathological analysis (Ovaries/ testes, kidneys, liver, lungs). The organs will be fixed using Bouin's (reproductive organs) and 10% neutral buffered formalin (kidneys, liver, spleen, lungs).Processing of tissue will be done by spin tissue processer, embedding of the tissue by tissue embedder. The tissues will be initially trimmed to 10-20µ thickness and later 3-6µ to obtain thinner tissue sections by using rotary microtome. Haematoxylin and Eosin staining will be performed for all tissues.

**Organ Weights**

Absolute weights of adrenal glands, brain, ovaries/testes, epididymis/uterus, heart, kidneys, liver, spleen and lungs will be recorded for all the animals after trimming adherent tissue immediately after dissection from the animal. Paired organs will be weighed together. Relative weights of these organs against fasting animal body weights will be calculated and reported.

**Data Compilation**

Data will be summarised in a tabular form showing the number of animals, experimental design, dose groups, dose volume and concentrations, test item and vehicle control details. All findings like clinical signs, mortality and morbidity data, time of death, body weights, feed consumption, clinical signs, and necropsy and pathology observations will be recorded and given in the final report. One original copy of the final report is issued to the sponsor.

**Statistical Analysis**

All the parameters of treated groups of both sex, viz. body weight, feed consumption, organ weights (absolute and relative), biochemical parameters, and hematology parameters will be analyzed using SPSS software, version 16.0 by using one-way ANOVA test with multiple comparison (vehicle controls treated groups) in the study report, and $p$ value $< 0.05$ is considered as statistically significant.

**References**

1. Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines for Laboratory Animal Facility, The Gazette of India, 1998.
2. Hayes AW, 2000. Principles and Methods of Toxicology, 4th ed., Taylor and Francis, London.
3. Karl-Heinz Diehl, R. H. (2001). A Good Practice Guide to the Administration of Substances and Removal of Blood, Including Routes and Volumes. journal of applied toxicology , 15-23.
4. OECD – 407 - Repeated dose 28-day oral Toxicity Study in Rodents, Adopted October 3, 2008.
5. Schedule – Y, Amendment version 2005, Drugs and Cosmetics Rules, 1945.

## MATERIALS AND METHODS

### ESTIMATION OF HEMATOLOGICAL PARAMETERS: [1]

**Collection of blood for hematological studies**

After the treatment period the animals were anaesthetized by ketamine hydrochloride and the blood was collected from Retro-orbital sinus by using capillary into a centrifugation tube which contains EDTA for haematological parameters The haematological parameters like RBC, WBC and Hb percentage, Differential cell count, MCV, MCHC, Hematocrit, MCH, platelet count were estimated by the following procedures.

**1. ENUMERATION OF RED BLOOD CELLS: [1]** Ramnic 2007)

Reagents : RBC diluting fluid

**Procedure:**

Using a red blood cell pipette of haemocytometer, well mixed blood was drawn up to 0.5 mark and RBC diluting fluid was taken up to mark II. The fluid blood mixture was shaken and transferred onto the counting chamber. The cells were allowed to settle to the bottom of the chamber for 2 min. See the fluid does not get

dried. Using 45X or high power objective the RBC's were counted uniformly in the larger corner squares.

The cells were expressed as number of cells $x10^{12}$/l

**2. ENUMERATION OF WBC: [2] John 1972)**

**Reagents:**

Turk's fluid: Turk's fluid was prepared by mixing 2ml of acetic acid with 100 ml of distilled water. To this 10 drop of aqueous methylene blue 3 % w/v) was added. This solution haemolysis the red cells due to acidity so that counting of white cells becomes easy.

**Procedure:**

Using a white blood cell pipette of haemocytometer, well mixed blood was drawn up to 0.5 mark and WBC diluting fluid was taken up to mark II. The fluid blood mixture was shaken and transferred onto the counting chamber. The cells were allowed to settle to the bottom of the chamber for 2 min. See the fluid does not get dried.

Using 10X or low power objective the WBC's were counted uniformly in the larger corner squares.

The cells were expressed as number of cells/10mm.

**3. DIFFERENTIAL LEUCOCYTE COUNT: [3] JOHN 1972)**

**Reagent:**

Leishmann's stain: 150mg of powdered leishmann's stain was dissolved in 133ml of acetone free methanol.

**Procedure:**

A blood film stained with leishmann's stain was examined under oil immersion and the different types of WBCs were identified. The percentage

distribution of these cells was then determined. Smears were made from anticoagulant blood specimens and stained with leishmann's stain. The slides were preserved for counting the number of lymphocytes and neutrophils, per 100 cells were noted.

From the different Leukocyte count and WBC count, absolute lymphocyte and neutrophil count were calculated.

$$\text{Absolute neutrophil count} = \frac{\text{Number of neutrophils}}{100} \times \text{TWBC}$$

$$\text{Absolute lymphocyte count} = \frac{\text{Number of lymphocytes}}{100} \times \text{TWBC}$$

**DETERMINATION OF BIOCHEMICAL PARAMETERS:**

For assessment of biochemical parameters, blood samples were collected from the animals by puncturing the retro-orbital plexus and centrifuged. The serum collected after centrifugation was analyzed for various biochemical parameters like SGOT, SGPT, ALP,TC.TG,HDL All of the above biochemical parameters were estimated using semi autoanalyzer (Photometer 5010 $_{V5+}$, Germany) with enzymatic kits procured from Piramal Healthcare limited, Lab Diagnostic Division, Mumbai, India.

**1. Total Cholesterol (TC)**

**Principle**

Determination of cholesterol is done after enzymatic hydrolysis and oxidation. The colorimetric indicator is quinoneimine, which is generated from 4-aminoantipyrine and phenol by hydrogen peroxide under the catalytic action of peroxidase (trinder's reaction).

Cholesterol ester + $H_2O$ $\xrightarrow{CHE}$ Cholesterol + Fatty acid

Cholesterol + $O_2$ $\xrightarrow{CHO}$ Cholesterol-3-one + $H_2O_2$

$2H_2O_2$ + 4- Amino antipyrine + Phenol $\xrightarrow{POD}$ Quinonelimine + 4 $H_2O_2$

**Method**

CHOD-PAP: Enzymatic photometric test

**Table 6: Reagents**

| | |
|---|---|
| Goods buffer (pH 6.7) | 50 mmol/ l |
| Phenol | 5 mmol/l |
| 4-aminoantipyrine | 0.3 mmol/l |
| Cholesterol estrase | > 200 U/l |
| Cholesterol oxidase | > 100 U/l |
| Peroxidase | 3 KU/l |
| Standard | (5.2 mmol/l) |

**Assay procedure**

a. 1 ml (1000 µl) of reagent-1 is taken in a 5 ml test tube.
b. Added 0.01 ml (10 µl) of serum.
c. Mixed well and incubated at 37°C for 5 min.
d. Read the test sample.

**NORMAL RANGE: <** 200 mg/dl in serum.

1. Deeg R, Ziegenhorn J, Kinetic enzymatic method for automated determination of total cholesterol in serum, Clin. Chem., 1983, 29:1798-802.

**2. Triglycerides**

**Principle**

Determination of triglycerides (TG) alters enzymatic splitting with lipoprotein lipase. Indicator is quinoneimine which is generated from 4-aminoantipyrine and 4-chlorophenol by hydrogen peroxidase under the catalytic action of peroxidase.

Triglycerides $\xrightarrow{LPL}$ Glycerol + fatty acid

Glycerol + ATP $\xrightarrow{GK}$ Glycerol-3-phosphate+ ADP

Glycerol-3-phosphate +$O_2$ $\xrightarrow{GPO}$ Dihydroxyaceton phosphate + $H_2O_2$

$2H_2O_2$ + 4- Amino antipyrine + 4- chlorophenol $\xrightarrow{POD}$ Quinonelimine + HCL + $4H_2O_2$

**Method**

Colorimetric enzymatic test using glycerol-3-phosphate-oxidase (GPO).

**Reagents**

Components and concentrations in the test Goods buffer pH 7.2, 50 mmol/ l

**Table 7: Reagents**

| | |
|---|---|
| 4-chloroPhenol | 4 mmol/l |
| ATP | 2 mmol/l |
| $Mg^{2+}$ | 15 mmol/l |
| Glycerokinase | > 0.4 Kμ/l |
| Peroxidase | > 2 Kμ/l |
| Lipoprotein lipase | > 4 Kμ/l |
| 4-aminoantipyrine | 0.5 mmol/l |
| Glcerol-3-phosphate- oxidase | > 1.5Kμ/l |
| Standard | (2.3 mmol/l) |

**Assay procedure**

a. 1 ml (1000 μl) of reagent-1 is taken in a 5 ml test tube.
b. Added 0.01 ml (10 μl) of serum.
c. Mixed well and incubated at 37°C for 15 min.
d. Read the test sample.

**Normal Range: <** 200 mg/dl in serum.

1. Cole T.G, Klotzsch S.G, Mcnarmara J, Measurement of triglyceride concentration, In Rifai N, Warnick G.R, Dominiczak M.H, Handbook of lipoprotein testing, Washington:AACC, Press, 1997, 115-26.

**3. HDL Cholestrol**

**Principle**

Chylomicrons, VLDL and LDL are precipitated by adding phosphotungstic acid and magnesium ions to the sample. Centrifugation leaves only the HDL in the supernatant. The cholesterol content in it is determined enzymatically.

**Method**

Phosphotungstic acid precipitation method.

**Table 8: Reagents**

| | |
|---|---|
| Phosphotungstic acid | 0.55 mmol/l |
| Magnesium chloride | 25 mmol/l |

**Assay procedure**

**A. Preparation of supernatant for the HDL-CHL estimation**

Added 200 µl of serum to the 500 µl of HDL-Cholesterol precipitating reagent (from HDL kit) in 1.5 ml centrifuge tube and mixed well. Centrifuged the above solution at 4000 rpm for 10 min.

**B. Preparation of test sample for the estimation of HDL-Cholesterol**

a. Taken 1000 µl of reagent-1 (from cholesterol kit) in a 5 ml test tube.
b. Added, 100 µl of supernatant from above centrifuged solution
c. Mixed well and incubated at 37°C for 15 min.
d. Read the test sample.

**Normal Range: >** 60 mg/dl in serum.

1. Friedewald W.T, Levy R.T, Frederickson D.S, Estimation of VLDL and LDL cholesterol, Clin. Chem., 1972, 18:499-502.

## ESTIMATION OF SERUM GLUTAMATE PYRUVATE TRANSAMINASES (SGPT/ ALT)

### 1. Determination of aspartate aminotransferase (AST)

Aspartate aminotransferase, also known as Glutamate Oxaloacetate Transaminase (GOT) catalyses the transamination of L-aspartate and α keto glutarate to form oxaloacetate and L- glutamate. Oxaloacetate formed is coupled with 2,4-Dinitrophenyl hydrazine to form hydrazone, a brown coloured complex in alkaline medium which can be measured colorimetrically.

### Reagents

Buffered aspartate (pH 7.4); 2,4- DNPH reagent; 4N sodium hydroxide; working pyruvate standard; solution I (prepared by diluting 1 ml of reagent 3 to 10 ml with purified water).

### Procedure

Rietman and Frankle method was adopted for the estimation of SGOT. (Reitmann S, Frankel S, 1957. A colorimetric method for the determination of serum oxaloacetic and glutamic pyruvate transminases. American Journal of Clinical Pathology.28: 56-63.The reaction systems used for this study included blank, standard, test (for each serum sample) and control (for each serum sample). 0.25 ml of buffered aspartate was added into all the test tubes. Then 0.05 ml of serum was added to the test group tubes and 0.05 ml of working pyruvate standard into the standard tubes. After proper mixing, all the tubes were kept for incubation at $37^{o}$C for 60 min, after which 0.25 ml each of 2,4- DNPH reagent was added into all the tubes. Then, 0.05 ml of distilled water and 0.05 ml of each serum sample was added to the blank and the serum control tubes respectively. The mixture was allowed to stand at room temperature for 20 min. After incubation, 2.5 ml of solution I was added to all test tubes. Mixed properly and optical density was measured in a spectrophotometer at 505 nm within 15 min.

The enzyme activity was calculated as:-

AST (GOT) activity in IU/L) = [(Absorbance of test **-** Absorbance of control)/ (Absorbance of standard - Absorbance of blank)] x concentration of the standard

**2. Determination of alanine aminotransferase (ALT)**

Alanine aminotransferase, also known as Glutathione Peroxidase (GPT) catalyses the transamination of L-alanine and α keto glutarate to form pyruvate and L-Glutamate. Pyruvate so formed is coupled with 2,4 – Dinitrophenyl hydrazine to form a corresponding hydrazone, a brown coloured complex in alkaline medium which can be measured colorimetrically.

**Reagents**

Buffered alanine (pH 7.4), 2,4–DNPH, 4N sodium hydroxide, working pyruvate standard, solution I (prepared by diluting 1 ml of reagent 3 to 10 ml with purified water).

**Procedure**

Rietman and Frankle method was dopted for the estimation of SGPT. The reaction systems used for this study included blank, standard, test (for each serum sample) and control (for each serum sample). 0.25 ml of buffered alanine was added into all the test tubes. This was followed by the addition of 0.05 ml of serum into the test group tubes and 0.05 ml of working pyruvate standard into the standard tubes. After proper mixing, all the tubes were kept for incubation at 37$^{o}$C for 60 minutes, after which 0.25 ml each of 2,4- DNPH reagent was added into all the tubes. Then, 0.05 ml of distilled water and 0.05 ml of each serum sample was added to the blank and the serum control tubes respectively. The mixture was allowed to stand at room temperature for 20 min. After incubation, 2.5 ml of solution **I** was added to all test tubes. Mixed properly and optical density was read against purified water in a spectrophotometer at 505 nm within 15 min.

The enzyme activity was calculated as:- ALT (GPT) activity in IU/L) = [(Absorbance of test **-** Absorbance of control)/ (Absorbance of standard - Absorbance of blank)] x concentration of the standard.

**3. Determination of alkaline phosphatase (ALP)**

Alkaline phoshatase from serum converts phenyl phosphate to inorganic phosphate and phenol at pH 10.0. Phenol so formed reacts in alkaline medium with 4-aminoantipyrine in presence of the oxidising agent potassium ferricyanide and forms an orange-red coloured complex, which can be measured spectrometrically. The color intensity is proportional to the enzyme activity.

**Reagents:**

Buffered substrate

Chromogen Reagent

Phenol Standard, 10 mg%

**Procedure:**

ALP was determined using the method of Kind (Kind PRM, King EJ, 1972. *In-vitro* determination of serum alkaline phosphatase. Journal of Clinical Pathology 7: 321-22\). The working solution was prepared by reconstituting one vial of buffered substrate with 2.2 ml of water. 0.5 ml of working buffered substrate and 1.5 ml of purified water was dispensed to blank, standard, control and test. Mixed well and incubated at $37^0$C for 3 min. 0.05 ml each of serum and phenol standard were added to test and standard test tubes respectively. Mixed well and incubated for 15 min at $37^0$C. Thereafter, 1 ml of chromogen reagent was added to all the test tubes. Then, added 0.05 ml of serum to control. Mixed well after addition of each reagent and the O.D of blank, standard, control and test were read against purified water at 510 nm.

Serum alkaline phosphatase activity in KA units was calculated as follows

[(O.D. Test-O.D. Control) / (O.D. Standard- O.D. Blank)] x 10

**4. Determination of bilirubin**

In toxic liver, bilirubin levels are elevated. Hyperbilirubinemia can result from impaired hepatic uptake of unconjugated bilirubin, such a situation can occur in generalized liver cell injury, certain drugs (e.g Rifampin and probenecid) interfere with the rat uptake of bilirubin by the liver cell and may produce a mild unconjugated

hyperbilirubinemia. Bilirubin level rises in diseases of hepatocytes, obstruction to bilirubin excretion into duodenum, in haemolysis and defects of hepatic uptake and conjugation of Bilirubin pigment such as Gilbert's disease.

Elevation of total serum bilirubin may occur due to:

1. Excessive haemolysis or destruction of the red blood cells.Eg:Haemolytic disease of the new born.
2. Liver diseases.Eg.Hepatitis and cirrhosis.
3. Obstruction of the biliary tract.Eg.Gall stones.

The method is based on the reaction of Sulfonilic acid with sodium nitrite to form azobilirubin which has maximum absorbance at 546nm in the aqueous solution. The intensity of the color Produced is directly proportional to the amount of direct or total bilurubin concentration present in the sample.

**Reagents**

1. Diazo A-(Reagent-R1) :Ready to use

2. Diazo B-(Reagent-R2):Ready to use

3. Bilirubin Activater :Ready to use

**Procedure**

Kind & King's method was followed for the estimation of Bilirubin. Five hundred µl of working reagent was added to 50 µl of rat serum & incubated for 5 min at 37°C. Absorbance was measured AT 546 NM in semi auto analyzer against the standard.

The Bilirubin content was calculated using the following equation:

Total bilirubin (mg/dt) = Abs of the sample blank x 15.

Direct Bilirubin(mg/dt) = Abs of sample blank x 10.

## 5. ESTIMATION OF UREA

Urea is the nitrogen-containing end product of protein catabolism. States associated with elevated levels of urea in blood are referred to as hyper uremia or azotemia.

### Method

Estimation of urea was done by Urease-GLDH: enzymatic UV test.

### Principle

$$\text{Urea} + 2H_2O \xrightarrow{\text{Urease}} 2NH_4 + 2HCO_3$$

$$\text{2- Oxoglutarate} + NH_4^+ + \text{NADH} \xrightarrow{\text{GLDH}} \text{L- Glutamate} + NAD^+ + H_2O$$

**Table 14.** Reagents

| | | |
|---|---|---|
| R 1 | TRIS pH 7.8 | 120 mmol/l |
| | 2-Oxoglutarate | 7 mmol/l |
| | ADP | 0.6 mmol/l |
| | Urease | ≥ 6 KU/l |
| | GLDH | ≥ 1 KU/l |
| R 2 | NADH | 0.25 mmol |
| R 3 | Standard | 40 mg/dl |

### Procedure

a. Take 1000 µl of reagent-1 and 250 µl of reagent-2 in 5 ml test tube.
b. To this, add 10 µl of serum.
c. Mix well and immediately read the test sample at 340 nm Hg 334 nm Hg 365 nm optical path 1 cm against reagent blank (2-point kinetic).
d. And note down the value.

**Normal range:** 10 – 50 mg/dl.

## 6. ESTIMATION OF URIC ACID

Uric acid and its salts are end products of the purine metabolism. In gout the most common complication of hyperuricemia, ie. Increased serum levels of uric acid lead to formation of monosodium urate crystal around the joints.

**Method**

Enzymatic photometric test using TOOS (N ethyl- N (hydroxyl -3- sulfopropyl)-m-toluidin)

**Principle**

Uric acid + $H_2O$ + $O_2$ $\xrightarrow{\text{uricase}}$ Allantoin +$CO_2$ +$H_2O_2$

TOOS + 4 aminoantipyrine + $2H_2O_2$ $\xrightarrow{\text{POD}}$ Indamine + $3H_2O$

**Table** 15.reagents

| | | |
|---|---|---|
| R1 | Phosphate buffer pH 7.0 | 100mmol/l |
| | TOOS | 1mmol/l |
| | Ascorbate oxidase | ≥1 KU/l |
| R2 | Phosphate buffer pH 7.0 | 100mmol/l |
| | 4- amino antipyrine | 0.3mmol/l |
| | $K_4$ (Fe( CN)$_6$) | 10µmol/l |
| | Peroxidase | ≥1KU/l |
| | Uricase | ≥50U/l |

**Procedure**

a. Take 800µl of reagents -1 in a2ml centrifuge tube.
b. To this add 20µl of serum.
c. Mix well and incubate at 30°c for 5 minutes.
d. Then add 200µl of reagent2
e. Mix well incubate for 5min at 37°c
f. Measure the not down the values.

**Normal range:** 1.9-8.2mg/dl

**7. ESTIMATION OF CREATININE**:

**Principle:**

Creatinine forms a coloured complex with picrate in alkaline medium.

The rate of formation of the complex is measured.

**Reagents:**

Reagent 1 Standard Creatinine (2mg/100ml)

Reagent 2 Picric acid solution.

Reagent 3 sodium hydroxide solution

**Procedure:**

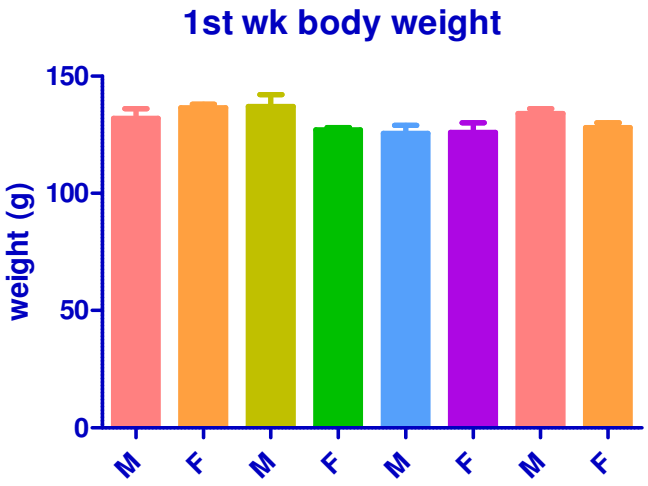
Take 500 µl of reagent -2 and 500 µl of reagent -3 in a 5ml test tube. To this add 100 µl of serum. Mix well and immediately read the test sample at Hg 492 nm 1cm light path and note down the values.

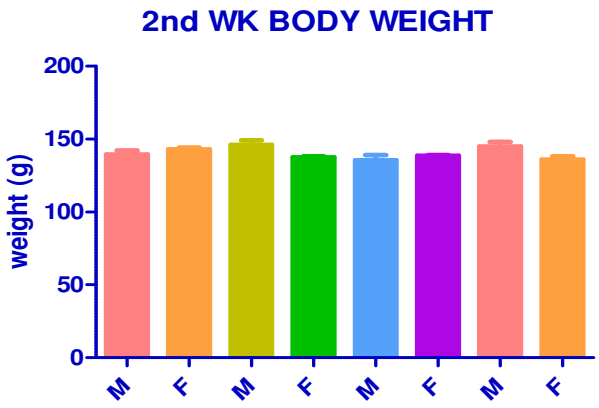
Normal range is 0.6 -1.1 mg/dl.

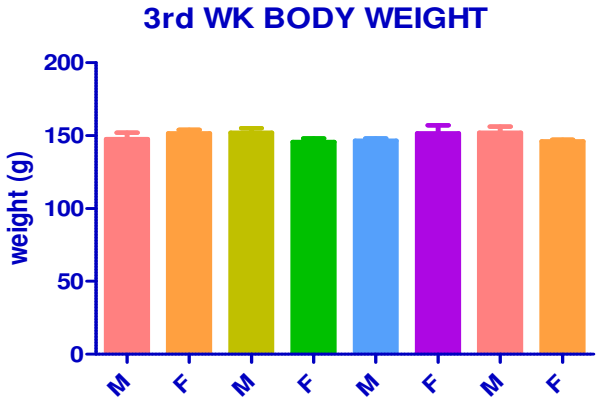
**TABLE: 1 EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAMON BODY WEIGHT IN Gram (PHYSICAL PARAMETER)**

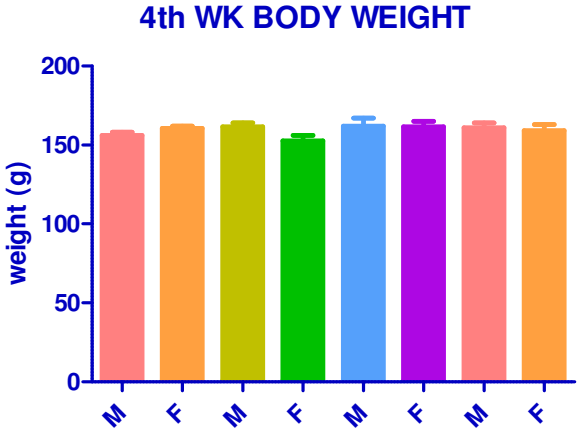
| GPs | Control | | Low Dose | | Middle Dose | | High Dose | |
|---|---|---|---|---|---|---|---|---|
| | Male | Female | Male | Female | Male | Female | Male | Female |
| 1st wk | 132±4 | 136.5±1.5 | 137±5 | 127±1 | 125.5±3.5 | 126±4 | 134±2 | 128±2 |
| 2nd wk | 139.5±2.5 | 143±1 | 146±3 | 137.5±0.5 | 135.5±3.5 | 138.5±0.5 | 145±3 | 136±2 |
| 3rd wk | 147.5±4.5 | 151.5±2.5 | 152±3 | 145.5±2.5 | 146.5±1.5 | 151.5±5.5 | 152±4 | 146±1 |
| 4th wk | 156±2 | 160.5±1.5 | 161.5±2.5 | 152.5±3.5 | 162±5 | 161.5±3.5 | 161±3 | 159±4 |

Values are expressed as the mean ± S.D




2nd WK BODY WEIGHT
weight (g)
200
150
100
50
0
M
F
M
F
M
F
M
F


3rd WK BODY WEIGHT
weight (g)
200
150
100
50
0
M
F
M
F
M
F
M
F

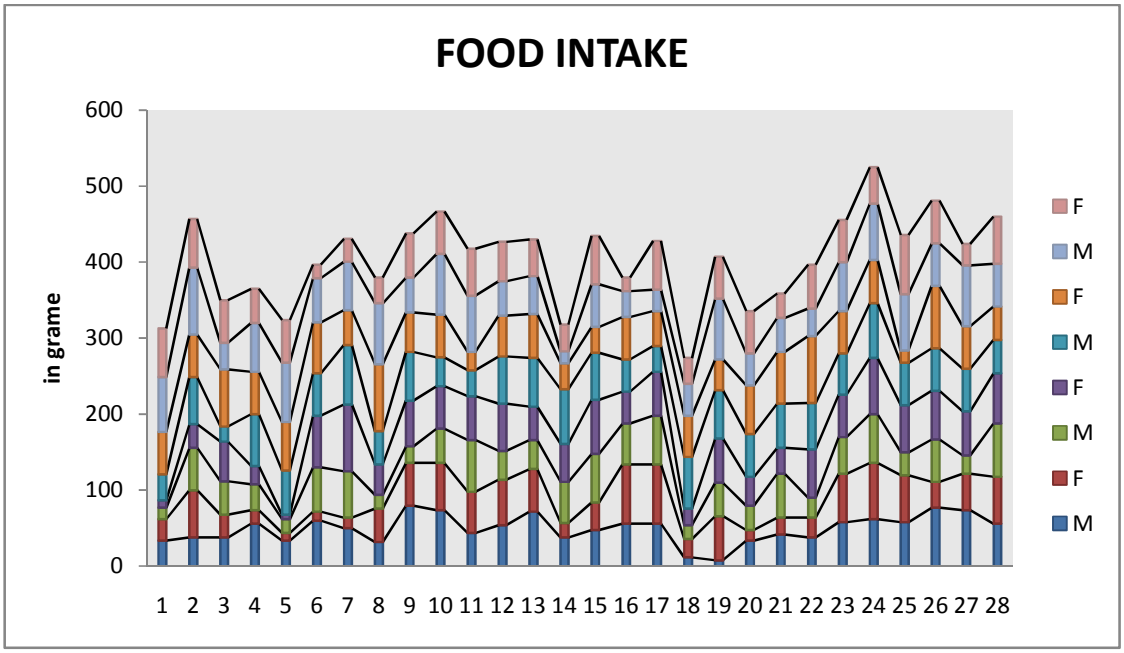

4th WK BODY WEIGHT
weight (g)
200
150
100
50
0
M
F
M
F
M
F
M
F

**EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM ON FOOD INTAKE In Gram**

| Groups | Control | | Low Dose | | Middle Dose | | High Dose | |
|---|---|---|---|---|---|---|---|---|
| DAY | Male | Female | Male | Female | Male | Female | Male | Female |
| Day 1 | 34 | 28 | 15 | 10 | 34 | 56 | 72 | 64 |
| DAY2 | 38 | 62 | 56 | 31 | 62 | 56 | 88 | 64 |
| DAY3 | 38 | 30 | 44 | 52 | 20 | 75 | 35 | 56 |
| Day 4 | 56 | 18 | 34 | 24 | 68 | 56 | 64 | 45 |
| DAY5 | 34 | 10 | 18 | 6 | 58 | 64 | 78 | 56 |
| Day 6 | 60 | 12 | 58 | 68 | 56 | 67 | 58 | 18 |
| DAY7 | 50 | 14 | 61 | 88 | 78 | 46 | 64 | 30 |
| DAY8 | 32 | 44 | 18 | 40 | 44 | 88 | 80 | 34 |
| Day 9 | 80 | 56 | 22 | 60 | 64 | 52 | 46 | 58 |
| DAY10 | 74 | 62 | 45 | 56 | 38 | 56 | 80 | 56 |
| Day 11 | 44 | 54 | 68 | 58 | 34 | 24 | 74 | 62 |
| DAY12 | 54 | 60 | 38 | 62 | 62 | 54 | 45 | 52 |
| DAY13 | 72 | 56 | 38 | 44 | 64 | 58 | 50 | 48 |
| Day 14 | 38 | 19 | 54 | 50 | 72 | 34 | 16 | 35 |
| DAY15 | 48 | 36 | 64 | 71 | 62 | 34 | 56 | 64 |
| Day 16 | 56 | 78 | 54 | 42 | 42 | 56 | 34 | 18 |
| DAY17 | 56 | 78 | 64 | 58 | 34 | 46 | 28 | 64 |
| DAY18 | 12 | 24 | 18 | 22 | 68 | 54 | 42 | 34 |
| Day 19 | 8 | 58 | 44 | 58 | 64 | 40 | 80 | 55 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| DAY20 | 34 | 14 | 32 | 38 | 56 | 64 | 42 | 56 |
| DAY21 | 42 | 22 | 58 | 34 | 58 | 68 | 45 | 32 |
| Day 22 | 38 | 26 | 26 | 64 | 61 | 88 | 36 | 58 |
| DAY23 | 58 | 64 | 48 | 56 | 54 | 56 | 64 | 56 |
| DAY24 | 62 | 74 | 64 | 74 | 72 | 57 | 74 | 48 |
| Day 25 | 58 | 62 | 30 | 62 | 56 | 16 | 74 | 78 |
| DAY26 | 77 | 34 | 56 | 64 | 56 | 82 | 56 | 56 |
| DAY27 | 74 | 48 | 24 | 58 | 56 | 56 | 80 | 28 |
| DAY28 | 56 | 62 | 70 | 66 | 44 | 44 | 56 | 62 |

Values are expressed as the mean ± S.D

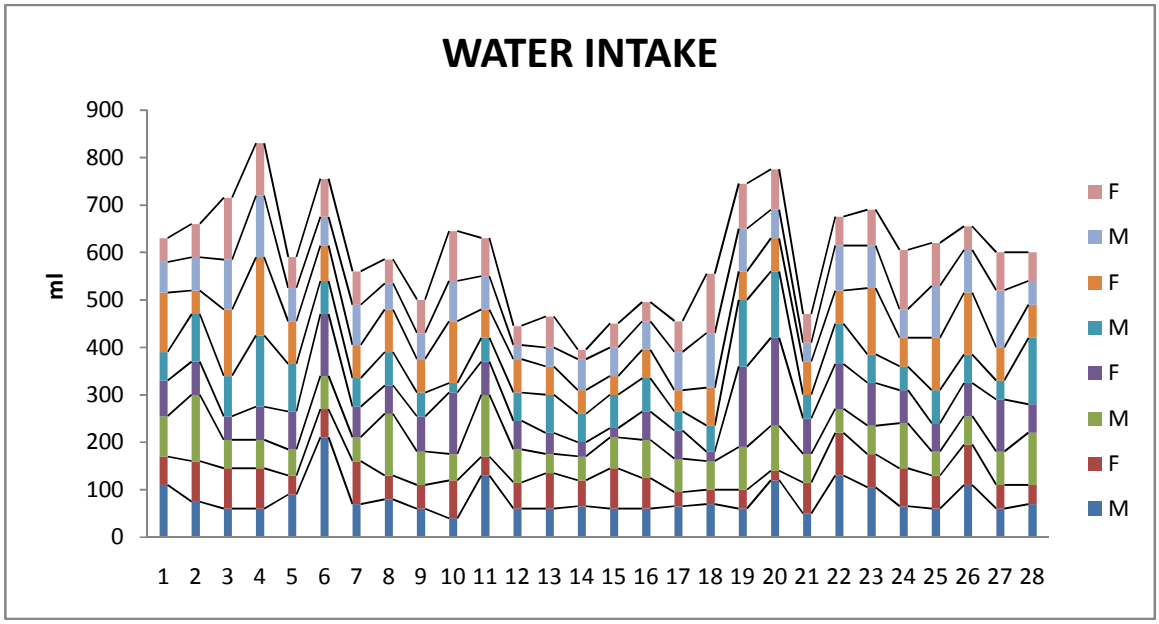


**EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAMON WATER INTAKE IN ml**

| Groups | Control | | Low Dose | | Middle Dose | | High Dose | |
|---|---|---|---|---|---|---|---|---|
| DAY | Male | Female | Male | Female | Male | Female | Male | Female |
| Day 1 | 110 | 60 | 85 | 75 | 60 | 125 | 65 | 50 |
| DAY2 | 75 | 85 | 140 | 70 | 100 | 50 | 70 | 70 |
| DAY3 | 60 | 85 | 60 | 50 | 85 | 140 | 105 | 130 |
| Day 4 | 60 | 85 | 60 | 70 | 150 | 165 | 130 | 110 |
| DAY5 | 90 | 40 | 55 | 80 | 100 | 90 | 70 | 65 |
| Day 6 | 210 | 60 | 70 | 130 | 70 | 75 | 60 | 80 |
| DAY7 | 70 | 90 | 50 | 65 | 60 | 70 | 85 | 70 |
| DAY8 | 80 | 50 | 130 | 60 | 70 | 90 | 55 | 50 |
| Day 9 | 60 | 50 | 70 | 75 | 50 | 70 | 55 | 70 |
| DAY10 | 40 | 80 | 55 | 130 | 20 | 130 | 85 | 105 |
| Day 11 | 130 | 40 | 130 | 70 | 50 | 60 | 70 | 80 |
| DAY12 | 60 | 55 | 70 | 60 | 60 | 70 | 30 | 40 |
| DAY13 | 60 | 75 | 40 | 45 | 80 | 60 | 40 | 65 |
| Day 14 | 65 | 55 | 50 | 30 | 60 | 50 | 65 | 20 |
| DAY15 | 60 | 85 | 65 | 20 | 70 | 40 | 60 | 50 |
| Day 16 | 60 | 65 | 80 | 60 | 70 | 60 | 60 | 40 |
| DAY17 | 65 | 30 | 70 | 60 | 40 | 45 | 80 | 65 |
| DAY18 | 70 | 30 | 60 | 20 | 55 | 80 | 115 | 125 |
| Day 19 | 60 | 40 | 90 | 170 | 140 | 60 | 90 | 95 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| DAY20 | 120 | 20 | 95 | 185 | 140 | 70 | 60 | 85 |
| DAY21 | 50 | 65 | 60 | 75 | 50 | 70 | 40 | 60 |
| Day 22 | 130 | 90 | 50 | 95 | 85 | 70 | 95 | 60 |
| DAY23 | 105 | 70 | 60 | 90 | 60 | 140 | 90 | 75 |
| DAY24 | 65 | 80 | 95 | 70 | 50 | 60 | 60 | 125 |
| Day 25 | 60 | 70 | 50 | 60 | 70 | 110 | 110 | 90 |
| DAY26 | 110 | 85 | 60 | 70 | 60 | 130 | 90 | 50 |
| DAY27 | 60 | 50 | 70 | 110 | 40 | 70 | 120 | 80 |
| DAY28 | 70 | 40 | 110 | 60 | 140 | 70 | 50 | 60 |

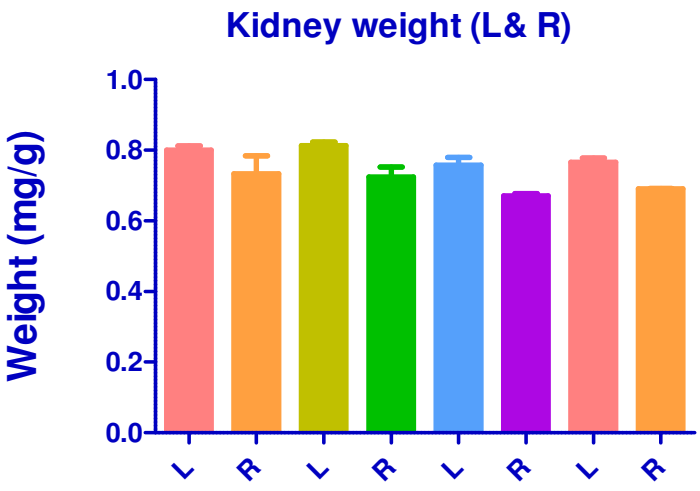
Values are expressed as the mean ± S.D

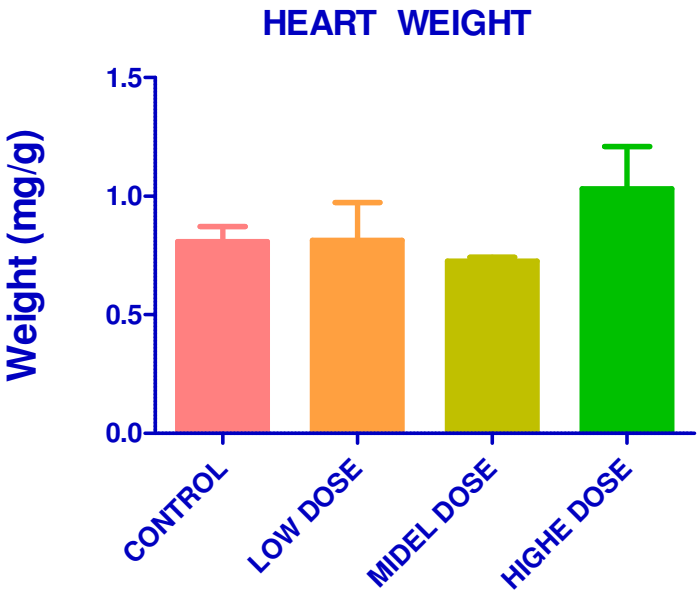


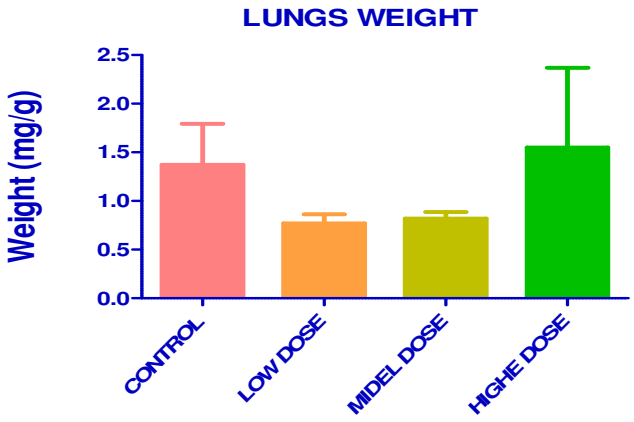
**EFFECT OF SUB-ACUTE DOSES (28 DAYS) OF SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAMON ORGAN WEIGHT** in gm

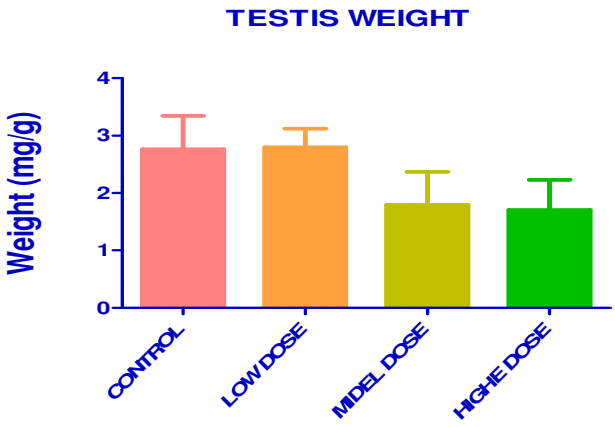
| GROUP | | CONTROL | Low Dose | Middle Dose | High Dose |
|---|---|---|---|---|---|
| LIVER WEIGHT | | 6.669±0.1905 | 6.117±0.663 | 6.251±0.3805 | 6.549±0.017 |
| KIDNEY WEIGHT | L | 0.8005±0.0115 | 0.813±0.01 | 0.758±0.022 | 0.7665±0.0115 |
| | R | 0.734±0.05 | 0.7245±0.0275 | 0.671±0.006 | 0.6905±0.0015 |
| HEART WEIGHT | | 0.808±0.064 | 0.8145±0.1585 | 0.7275±0.0155 | 1.032±0.177 |
| LUNGS WEIGHT | | 1.373±0.4195 | 0.7715±0.0915 | 0.8205±0.0655 | 1.549±0.8195 |
| TESTIS WEIGH | | 2.768±0.58 | 2.803±0.321 | 1.798±0.57 | 1.705±0.5225 |
| UTERUS | | 0.4755±0.0465 | 0.394±0.056 | 0.6675±0.0845 | 0.574±0.148 |

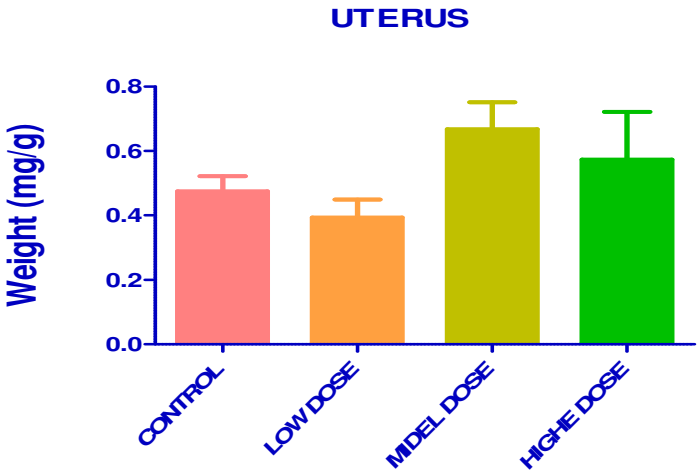
Values arae expressed as mean ± SEM Statistical significance (p) calculated by one way ANOVA followed by dunnett's (n=6); $^{ns}$p>0.05, *p<0.05, **p<0.01, ***p<0.001, calculated by comparing treated groups with control group.


Kidney weight (L& R)
Weight (mg/g)
1.0
0.8
0.6
0.4
0.2
0.0
L
R
L
R
L
R
L
R


HEART WEIGHT
Weight (mg/g)
1.5
1.0
0.5
0.0
CONTROL
LOW DOSE
MIDEL DOSE
HIGHE DOSE


LUNGS WEIGHT
Weight (mg/g)
2.5
2.0
1.5
1.0
0.5
0.0
CONTROL
LOW DOSE
MIDEL DOSE
HIGHE DOSE

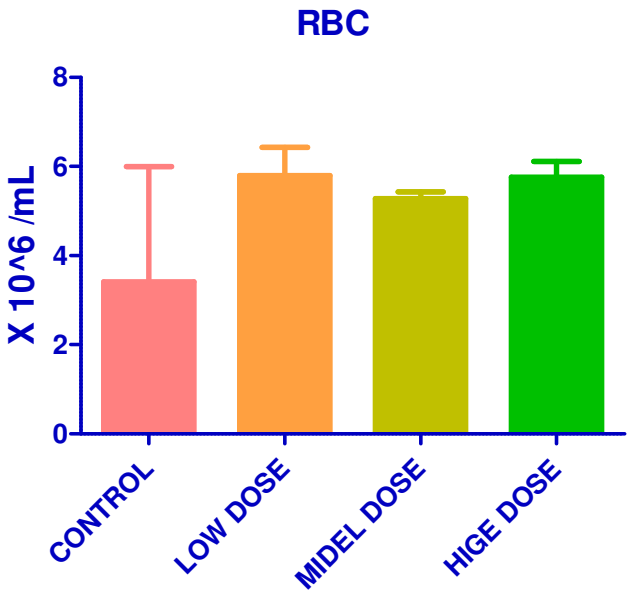

TESTIS WEIGHT
Weight (mg/g)
4
3
2
1
0
CONTROL
LOW DOSE
MIDEL DOSE
HIGHE DOSE

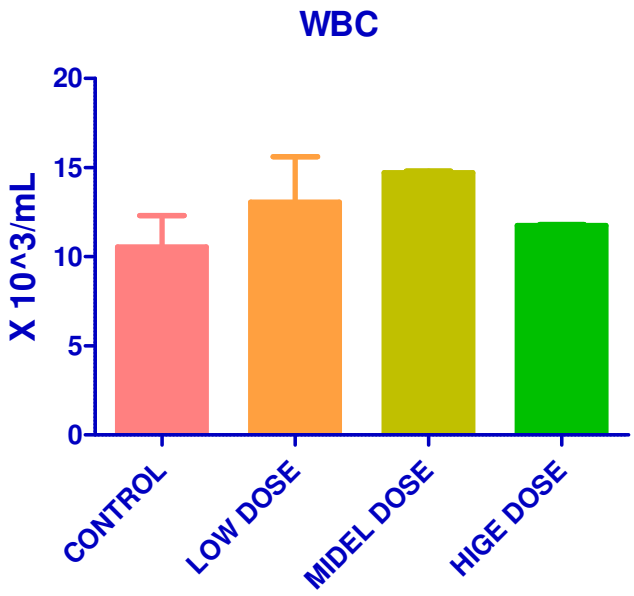

UTERUS
Weight (mg/g)
0.8
0.6
0.4
0.2
0.0
CONTROL
LOW DOSE
MIDEL DOSE
HIGHE DOSE

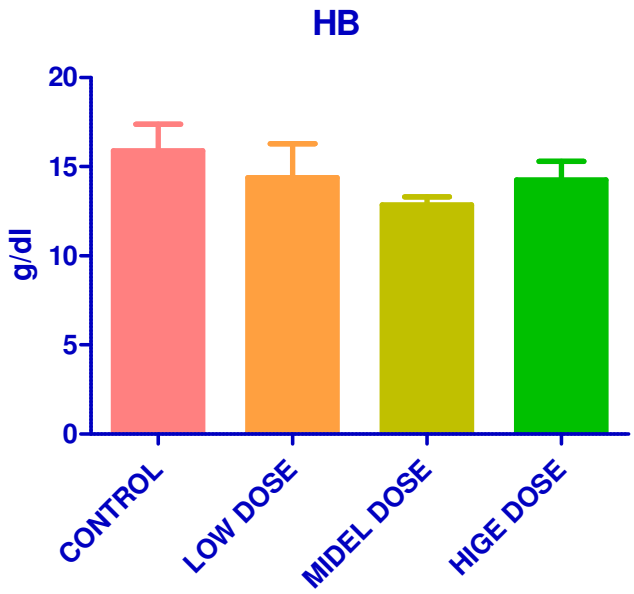
**EFFECT OF SUB ACUTE DOSES (28 DAY) 0F SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM ON HAEMATOLOGICAL PARAMETERS**

| Groups | Control | Low Dose | Middle Dose | High Dose |
|---|---|---|---|---|
| Rbc ($X10^6$/µl) | 3.41±2.59 | 5.795±0.635 | 5.28±0.15 | 5.765±0.345 |
| Wbc($X10^3$/µl) | 10.55±1.75 | 13.05±2.55 | 14.7±0.1 | 11.75±0.05 |
| Hb (g/dl) | 15.9±1.5 | 14.4±1.9 | 12.85±0.45 | 14.25±1.05 |

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



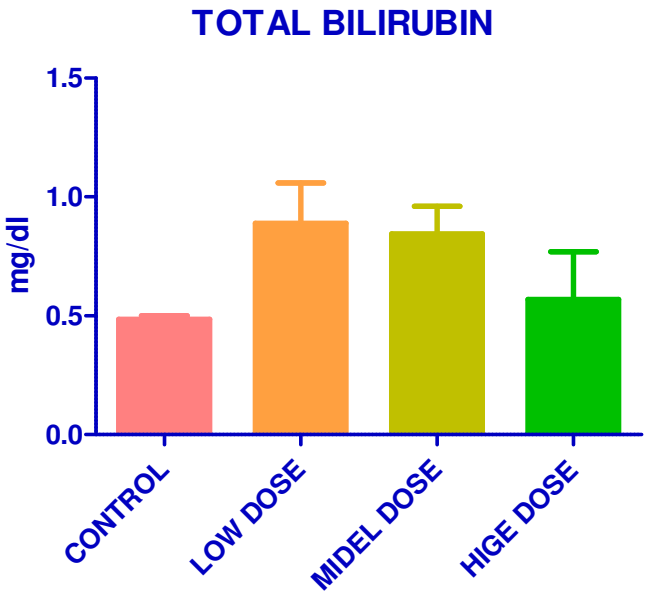

WBC
X 10^3/mL
20
15
10
5
0
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


HB
g/dl
20
15
10
5
0
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

**EFFECT OF SUB ACUTE DOSES (28 DAY) 0F SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAMON BIOCHEMICAL PARAMETER (LIVER PROFILE)**

| Groups | Control | Low Dose | Middle Dose | High Dose |
|---|---|---|---|---|
| Total Bilirubin(mg/dl) | 0.485±0.015 | 0.89±0.17 | 0.845±0.115 | 0.57±0.2 |

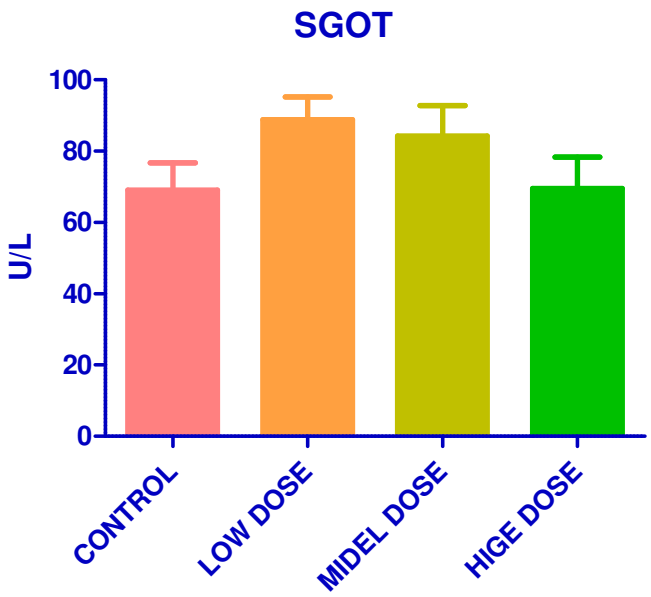
Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.

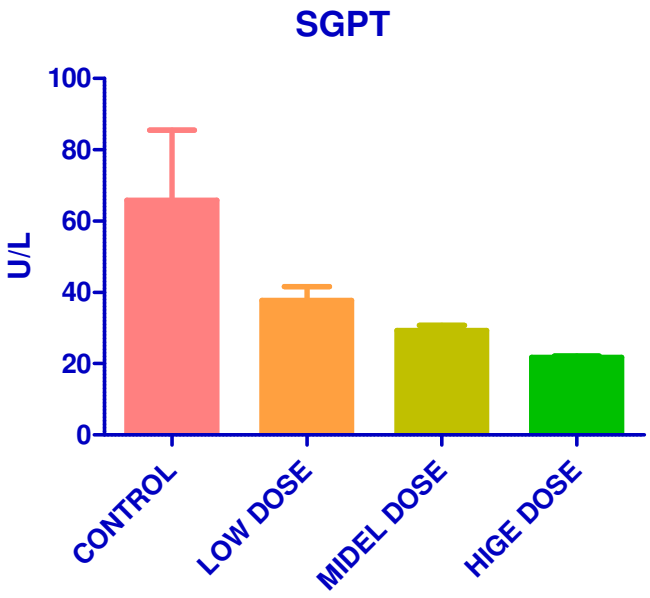


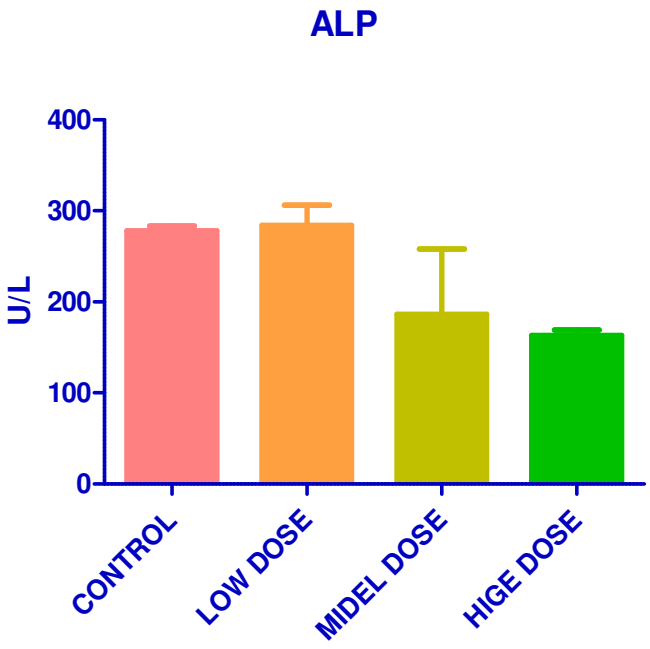
**EFFECT OF SUB ACUTE DOSES (28 DAY) 0F SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAMON BIOCHEMICAL PARAMETER (LIVER PROFILE)**

| Groups | Control | Low Dose | Middle Dose | High Dose |
|---|---|---|---|---|
| SGOT (U/L) | 69±7.7 | 88.8±6.4 | 84.3±8.5 | 69.5±8.8 |
| SGPT (U/L) | 65.9±19.6 | 37.75±3.85 | 29.25±1.55 | 21.8±0.3 |
| ALP (U/L) | 278.2±5.45 | 284.1±21.9 | 186.4±71.9 | 163.2±6 |

Values are expressed as the mean ± S.D; Statistical significance (p) calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



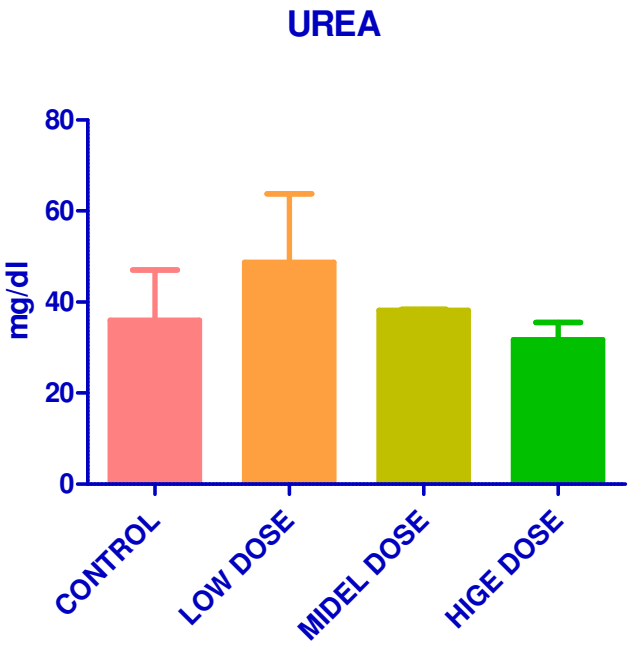

SGPT
100
80
60
40
20
0
U/L
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


ALP
400
300
200
100
0
U/L
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

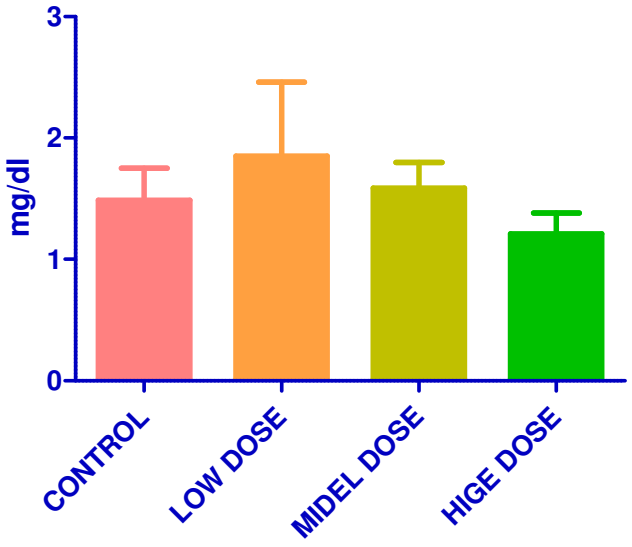
**EFFECT OF SUB ACUTE DOSES (28 DAY) 0F SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAMON BIOCHEMICAL PARAMETER (KIDNEY PROFILE)**

| Groups | Control | Low Dose | Middle Dose | High Dose |
|---|---|---|---|---|
| Urea (mg/dl) | 36.03±11.01 | 48.75±15.05 | 38.17±0.27 | 31.69±3.815 |
| Uric acid (mg/dl) | 1.485±0.265 | 1.85±0.61 | 1.59±0.21 | 1.21±0.17 |
| Creatinine (mg/dl) | 0.31±0.03 | 0.305±0.025 | 0.2±0.05 | 0.23±0.03 |

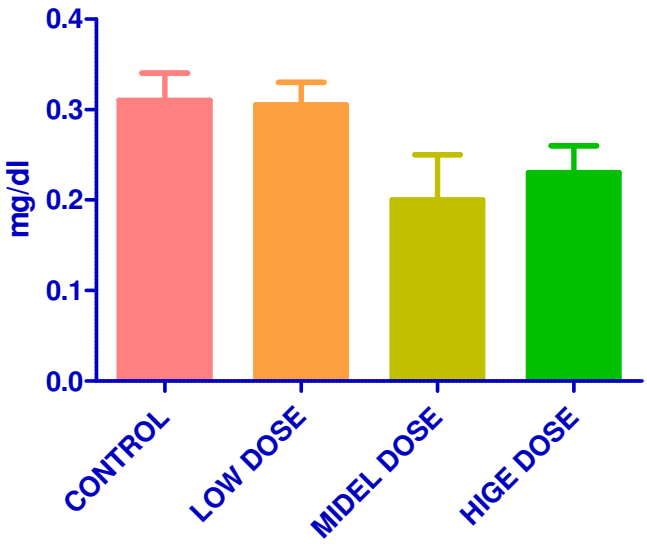
Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.



## URIC ACID



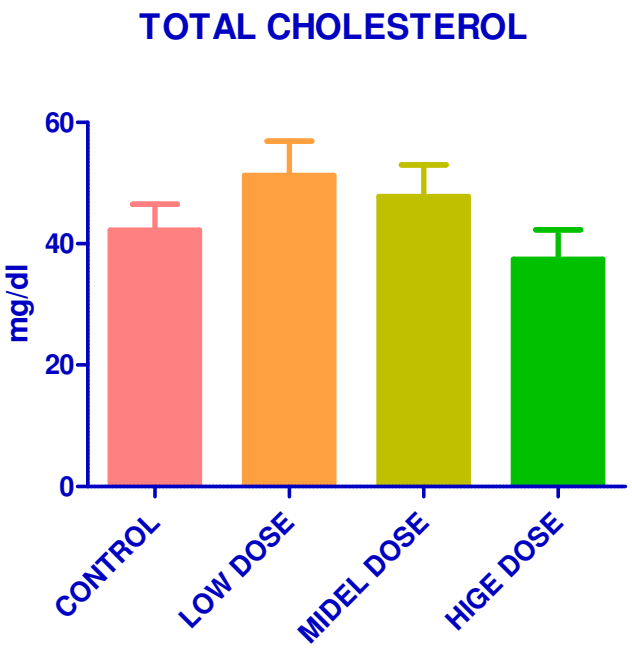

## CREATININE

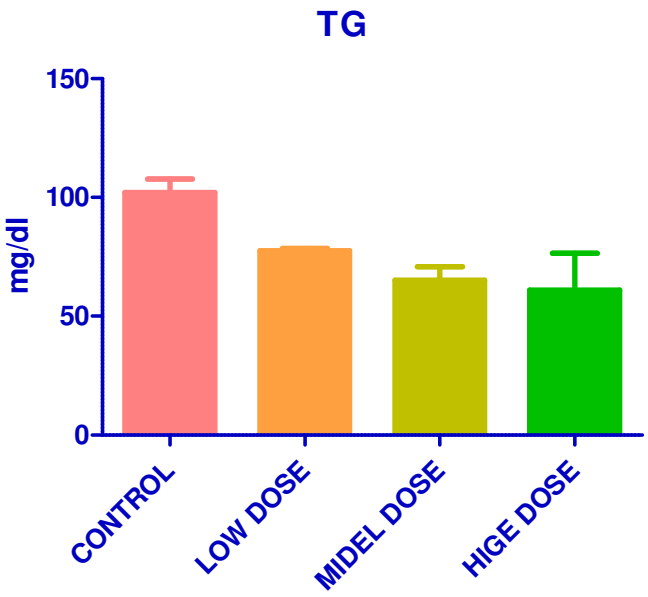


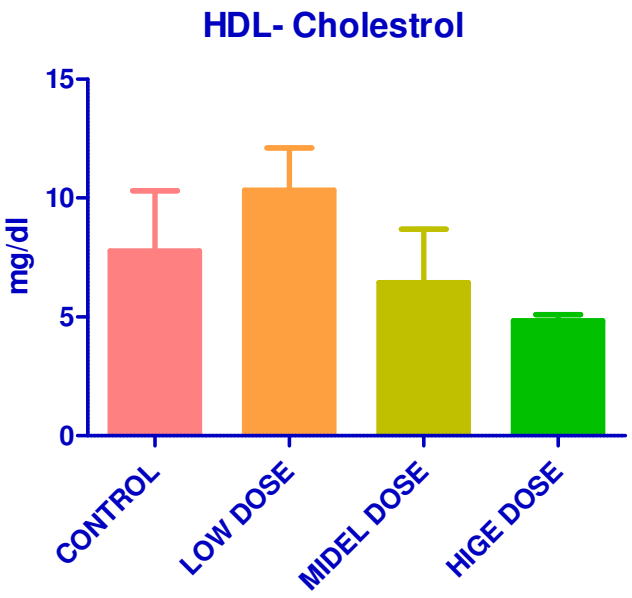
**EFFECT OF SUB ACUTE DOSES (28 DAY) 0F SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAMON BIOCHEMICAL PARAMETER (LIPID PROFILE)**

| Groups | Control | Low Dose | Middle Dose | High Dose |
|---|---|---|---|---|
| Total cholesterol (mg/dl) | 42.2±4.3 | 51.25±5.65 | 47.8±5.2 | 37.45±4.85 |
| Triglycerides (mg/dl) | 102.1±5.75 | 77.5±1.1 | 65.18±5.58 | 61±15.6 |
| HDL-Cholesterol (mg/dl) | 7.775±2.525 | 10.34±1.765 | 6.45±2.25 | 4.85±0.25 |

Values are expressed as the mean ± S.D; Statistical significance (p)calculated by one way ANOVA followed by dunnett's ns- no significant $^{*}P< 0.001$, $^{**}P < 0.01$, $^{***}P < 0.05$ calculate by comparing treated group with CONTROL group.




TG
150
100
50
0
mg/dl
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE


HDL- Cholestrol
15
10
5
0
mg/dl
CONTROL
LOW DOSE
MIDEL DOSE
HIGE DOSE

**RESULTS:**

**CLINICAL SIGNS:**

All animals in this study were free of toxic clinical signs throughout the dosing period of 28 days.

**Mortality:**

All animals in control and in all the treated dose groups survived throughout the dosing period of 28 days.

**Body weight:**

Results of body weight determination of animals Table-1 from control and different dose groups exhibited comparable body weight gain throughout the dosing period of 28 days.

**Food consumption:**

During dosing and the post-dosing recovery period, the quantity of food consumed by animals from different dose groups was found to be comparable with that by control animals.

**Organ Weight:**

Group Mean Relative Organ Weights (% of body weight) are recorded in Table No.4 Comparison of organ weights of treated animals with respective control animals on day 29 was found to be comparable similarly.

**Hematological investigations:**

The results of hematological investigations (Table 4) conducted on day 29 revealed following significant changes in the values of different parameters investigated when compared with those of respective controls; however, the increase or decrease in the values obtained was within normal biological and laboratory limits or the effect was not dose dependent.

**Biochemical Investigations:**

Results of Biochemical investigations conducted on days 29 and recorded in Table 2 revealed the following significant changes in the values of hepatic serum enzymes studied. When compared with those of respective control. However, the increase or decrease in the values obtained was within normal biological and laboratory limits.

**Histopathology:**

In histopathological examination, revealed normal architecture in comparison with control and treated animal.

**DISCUSSION:**

1) All the animals from control and all the treated dose groups up to 500 mg/kg survived throughout the dosing period of 28 days.

2) No signs of toxicity were observed in animals from different dose groups during the dosing period of 28 days.

3) Animals from all the treated dose groups exhibited comparable body weight gain with that of controls throughout the dosing period of 28 days.

4) Food consumption of control and treated animals was found to be comparable throughout the dosing period of 28 days

5) Haematological analysis conducted at the end of the dosing period on day 29, revealed no abnormalities attributable to the treatment.

6) Biochemical analysis conducted at the end of the dosing period on day 29 no abnormalities attributable to the treatment.

7) Organ weight data of animals sacrificed at the end of the dosing period was found to be comparable with that of respective controls.

8) Histopathological examination revealed normal architecture in comparison with control and treated animal.

**SUMMARY AND CONCLUSION:**

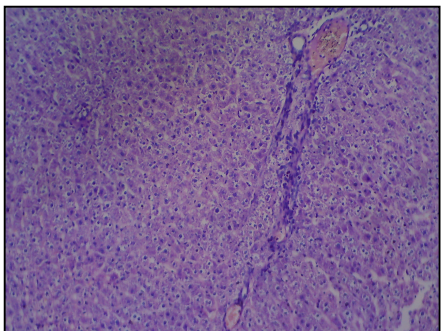
In conclusion **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** can be considered safe, as it did not cause either any lethality or adverse changes with general behavior of rats and also there were no observable detrimental effects (100 to 300 mg/kg body weight) over a period of 28 days. Our results have demonstrated that the **SANTHIRA PRAGASA MATHIRAI WITH CHUKKU KASAYAM** is relatively safe when administered orally in rats.

## 9.0 ABBRVIATION

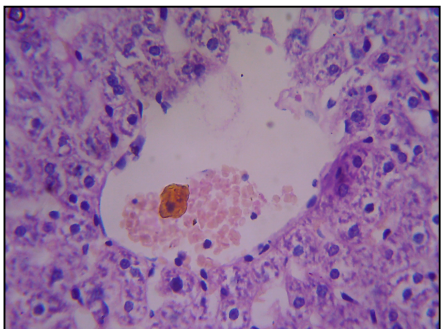
| | |
|---|---|
| No. | Number |
| Mg | Milligram |
| Kg | Kilogram |
| $LD_{50}$ | Lethal Dose $_{50}$ |
| p.o. | peros |
| mL | Milliliter |
| % | percentage |
| R&D | Research and Development |
| EDTA | Ethylene Diamine Tetra Acetic Acid |
| M | Male |
| g% | Gram percentage |
| g | Gram |
| NOAEL | No-Observed-Adverse-Effect-Level |
| MLD | Minimum Lethal Dose |
| MTD | Maximum Tolerated Dose |
| OECD | Organisation of Economic Co-operation and Development |
| CPCSEA | Committee for the Purpose of Control and Supervision of Experiments on Animals |

**HISTOPATHOLOGY - TOXICITY STUDY**

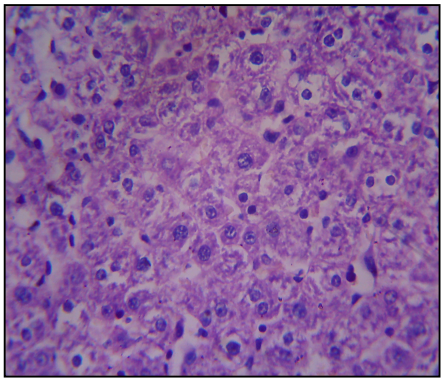
**SPECIMEN : A) Liver. Group –** : Santhira Pragasa Mathirai.



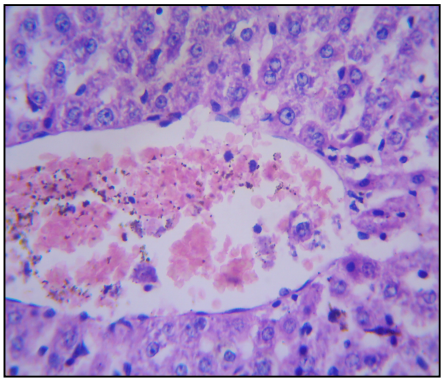
*10x shows mild loss of architecture*



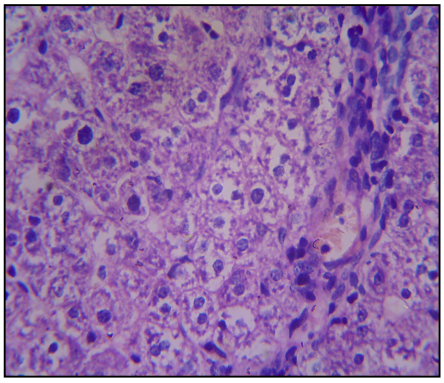
*40x shows central vein congestion*



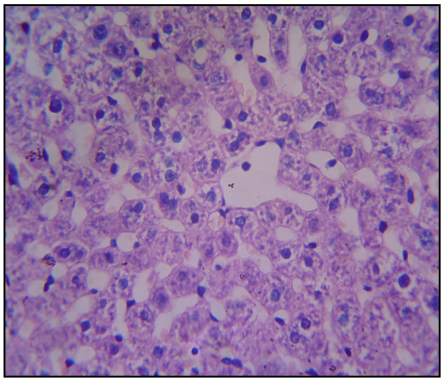
*40x shows bile uct hyperplasa*



*40x shows cytoplasmic vacuolation and binucleation*



*40x shows periportal inflammation*



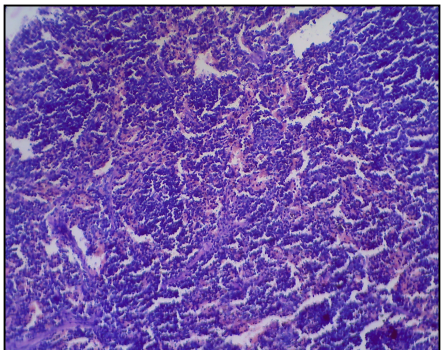
*40x shows sinusoidal dilatation*

**MICROSCOPIC APPEARANCE:**

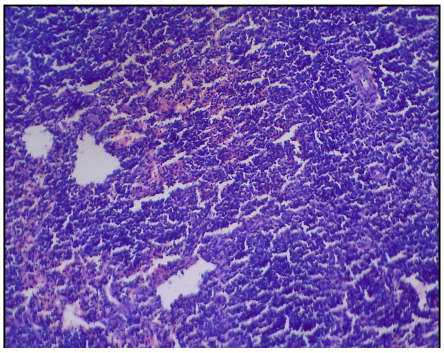
Section from liver shows lobular architecture with interface hepatitis. Individual Hepatocytes shows reactive atypia. Portal triad shows no significant pathology. Central vein and Sinusoids show dilatation.

**SPECIMEN : B) spleen.**

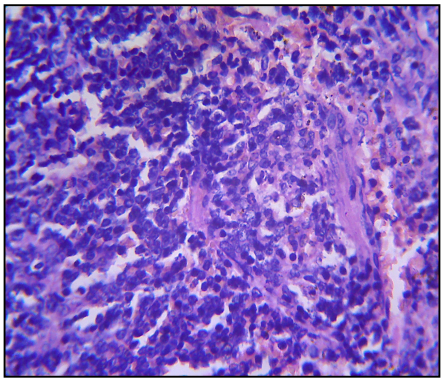
**Group –** : Santhira Pragasa Mathirai



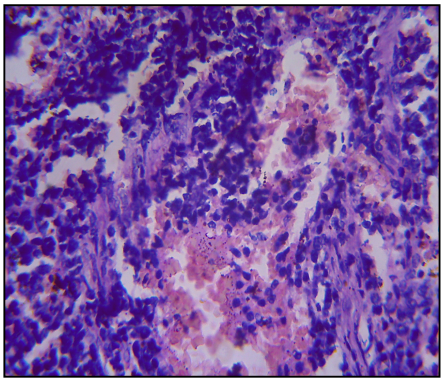
*10cx shows normal red pulp and white pulp*



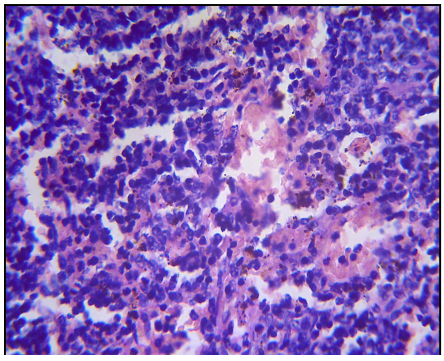
*10x shows spleen with normal morphology*



*40x shows normal lwhite pulp*



*40x shows normal white pulp and red pulp with pigment laden macrophages*



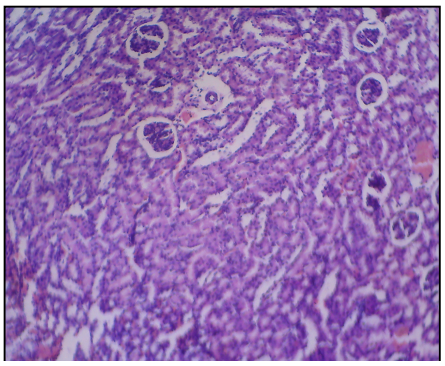
*40x shows white pulp with lymphocytic infiltrates and white pulp*

**MICROSCOPIC APPEARANCE:**

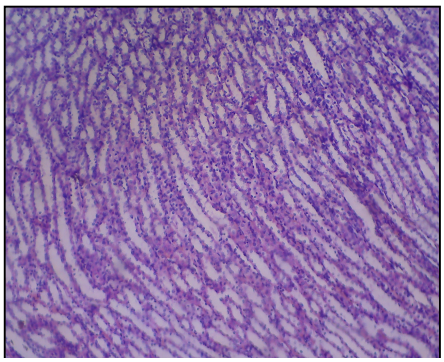
Section studied from spleen shows normal white pulp and red pulp. Red pulp shows pigment laden macrophages and congested vessels. White pulp shows lymphocytic infiltrates forming germinal centre. The pencillar artery shows normal morphology. Megakaryocytes

**SPECIMEN : C) Kidney.**

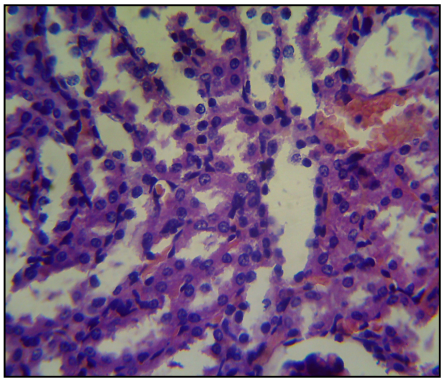
**Group –** : Vishnu chakra mathirai



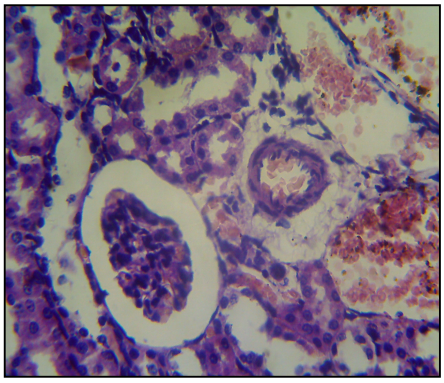
*10x shows kidney with both cortex and medulla*



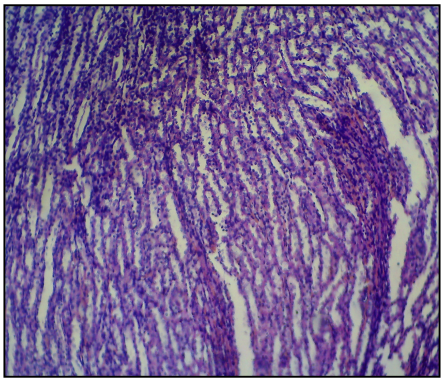
*10x shows normal interstitium*



*40x shows bllood vessels congestion*



*40x shows matrix expansion*



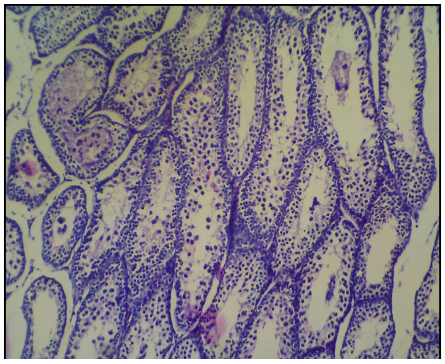
*40x shows normal interstitium*

**MICROSCOPIC APPEARANCE:**

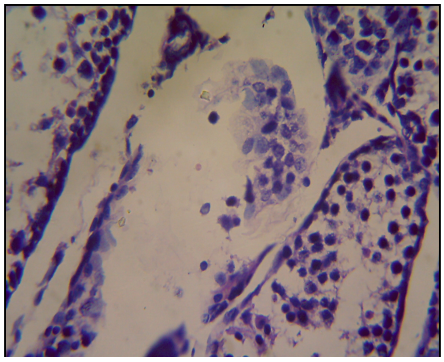
Section from kidney shows both cortex and medulla. Glomeruli and tubules shows no significant pathology. Interstitium shows no significant pathology. Blood vessels show congestion. There is no evidence of toxic changes.

**SPECIMEN : D) Testis**

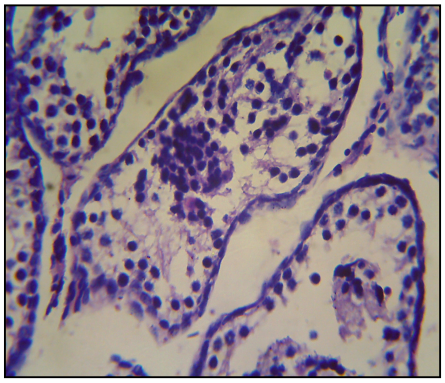
**Group –** : Santhira Pragasa Mathirai



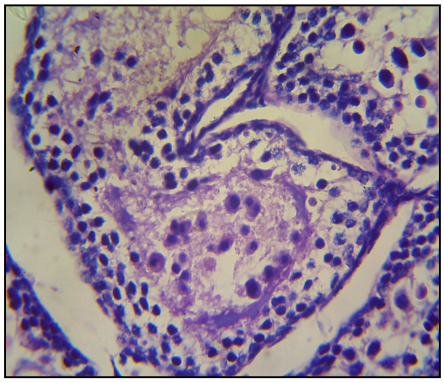
*10x shows testis with maturation arrest*



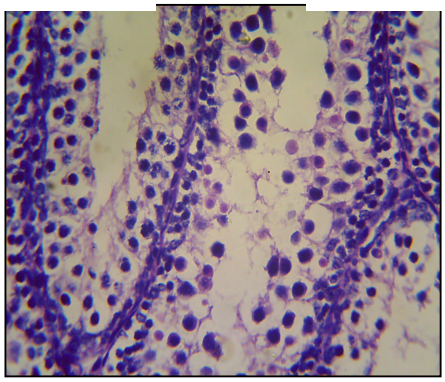
*40x shows lacking of spermatogenesis*



*40x shows maturation arreast*



*40x shows tubules (2)*



*40x shows tubules*

**MICROSCOPIC APPEARANCE:**

Section from testes with seminiferous tubules showing maturation arrest with lacking of spermatogenesis.

| | |
|---|---|
| **Name :**<br>**Ref. No. : [H0 326A/18]** | **Rec.On : 21/03/2018**<br>**Rep.On : 18/04/2018** |

**HISTOPATHOLOGY**

**SPECIMEN : Liver**

**Group –I** : Shanmuga priya- SPM .

**GROSS APPEARANCE:**

Received a specimen of liver measuring 3.0x2.2x1.2cms.

(PE): Two bits – One block.

**MICROSCOPIC APPEARANCE:**

Section from liver shows mild loss of architecture. Individual Hepatocytes shows binucleation, cytoplasmic vacuolation. Portal triad shows periportal inflammation and necrosis. Central vein shows congestion. Sinusoids show dilatation.

**Dr.C.R.Ajeethkumar.M.D. (Path).**

**Consultant pathologists:**
**Dr.S.Kalyani.M.D. (Path), Dr. C.R.Ajeeth kumar.M.D. (Path),**

Checked

| | |
|---|---|
| **Name :** | **Rec.On : 25/03/2018** |
| **Ref. No. : [H0 326B/17]** | **Rep.On : 18/04/2018** |

**HISTOPATHOLOGY**

**Toxicity study**

**SPECIMEN : B) spleen.**

**Group –I** : Shanmuga priya- SPM.

**GROSS APPEARANCE:**

Received a specimen of spleen measuring 2.4x0.8x0.4cms.

(PE): Two bits – One block.

**MICROSCOPIC APPEARANCE:**

Section studied from spleen shows normal white pulp and red pulp. Red pulp shows pigment laden macrophages and congested vessels. White pulp shows lymphocytic infiltrates forming germinal centre. The pencillar artery shows normal morphology. There is no evidence of toxic changes.

**Dr.C.R.Ajeeth kumar. M.D. (Path),**

**Consultant pathologists:**

**Dr.S.Kalyani.M.D. (Path), Dr. C.R.Ajeeth kumar.M.D. (Path),**

Checked

| | |
|---|---|
| **Name :** | **Rec.On : 25/03/2018** |
| **Ref. No. : [Ho 326C/18]** | **Rep.On : 18/04/2018** |

**HISTOPATHOLOGY**

**Toxicity study**

SPECIMEN : Kidney.

**Group – I** : Shanmuga priya- SPM.

GROSS APPEARANCE :

Received specimen of kidneys each measuring 1.3x0.6x0.5cms and 1.2x0.7x0.5cms.

PE : Two bits – One block.

MICROSCOPIC APPEARANCE:

Section from kidney shows both cortex and medulla. Glomeruli shows mesangeal matrix expansion and hypercellularity. Tubules show no significant pathology. Interstitium shows no significant pathology. Blood vessels show congestion.

- Focal segmental proliferative glomerulonephritis.

**Dr. C.R.Ajeeth kumar.M.D. (Path).**

**Consultant pathologists:**

**Dr.S.Kalyani.M.D. (Path), Dr. C.R.Ajeeth kumar.M.D. (Path),**

Checked

| | |
|---|---|
| **Name :** | **Rec.On : 25/03/2018** |
| **Ref. No. : [Ho 326D/18]** | **Rep.On : 18/04/2018** |

**HISTOPATHOLOGY**

**Toxicity study**

SPECIMEN : Testis.

**Group – I** : Shanmuga priya- SPM.

GROSS APPEARANCE :

Received specimen of both testis measuring each 1.0x0.6x0.5cms and 1.0x0.5x0.4cms.

PE : Two bits – One block.

MICROSCOPIC APPEARANCE:

Section from testes with seminiferous tubules shows maturation arrest with lacking of spermatogenesis. No evidence of granuloma/ malignancy.

**Dr. C.R.Ajeeth kumar.M.D. (Path).**

**Consultant pathologists:**

**Dr.S.Kalyani.M.D. (Path), Dr. C.R.Ajeeth kumar.M.D. (Path),**

Checked

## ANNEXURE – IV

## ASSESSMENT FORMS

| | |
|---|---|
| **FORM I** | **:** Screening and Selection Proforma |
| **FORM I A** | **:** History Proforma on Enrollment |
| **FORM II** | : Clinical assessment on enrollment |
| **FORM II A** | **:** Clinical assessment during and after trial |
| **FORM III** | : Laboratory Investigation on enrollment and conclusion of trial |
| **FORM IV** | : Consent Form |
| **FORM IV B** | : Withdrawal form |
| **FORM IV C** | : Patient information sheet |
| **FORM IV D** | : Dietary Advice form |
| **FORM IV E** | : Adverse Reaction form |
| **FORM IV F** | : Discharge proforma |

**GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL**

**POST GRADUATE DEPARTMENT**

**PALAYAMKOTTAI, TIRUNELVELI – 627002**

**BRANCH – III SIRAPPU MARUTHUVAM**

TO EVALUATE THE CLINICAL EFFICACY OF SIDDHA HERBO MINERAL FORMULATION "**SANTHIRA PRAGASA MATHIRAI**" INTERNAL & "**SEMBAI THYLAM**" EXTERNAL IN "**KUMBA VATHAM**" (PERIARTHRITIS OF SHOULDER).

**FORM I – SCREENING & SELECTION PROFORMA**

1. OP / IP NO : _____
2. NAME : _____
3. RELIGION : H / C / M / O
4. AGE / GENDER : _____
5. OCCUPATION : _____
6. INCOME : _____
7. CONTACT NO : _____
8. INCLUSION CRITERIA :

**INCLUSION CRITERIA**:

- Sex: Both Male and Female

- Patient having main symptoms of shoulder joint pain radiating towards upper arm and forearm, numbness, restricted movement of upper limb, loss of abduction and forward flexion followed by stiffness of the shoulder joints.
- Patient willing to sign the informed consent stating that he/she will consciously stick to the treatment during 20-30 days.
- Willing for doing laboratory investigations and X-Ray, imaging.
- Willing to cooperate with the proper clinical examination.

- Controlled Diabetes mellitus
- Controlled hypertension

**EXCLUSION CRITERIA:**

- Rheumatoid arthritis
- Ischaemic heart diseases
- Pregnancy and lactation
- Recent shoulder dislocation.
- Recent shoulder fracture.

ADMITTED TO TRIAL:

YES NO

If Yes Serial Number :

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

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TO EVALUATE THE CLINICAL EFFICACY OF SIDDHA HERBO MINERAL FORMULATION "**SANTHIRA PRAGASA MATHIRAI**" INTERNAL & "**SEMBAI THYLAM**" EXTERNAL IN "**KUMBA VATHAM**" (PERIARTHRITIS OF SHOULDER).

**FORM I A – HISTORY PROFORMA**

1. SL.NO : _____
2. OP / IP NO : _____
3. NAME : _____
4. RELIGION : H / C / M / O
5. AGE / GENDER : _____
6. OCCUPATION : _____
7. INCOME : _____
8. CONTACT NUMBER : _____
9. MARITAL STATUS : Married / Unmarried
10. COMPLAINTS & DURATION :

**11. PERSONAL HISTORY:**

| PERSONAL HABITS | YES | NO | IF YES SPECIFY DURATION |
|---|---|---|---|
| Smoking | | | |
| Tobacco Chewing | | | |
| Alcohol | | | |
| Narcotic Drug Addiction | | | |

**12. DRUG HISTORY:**

Whether the Patient has underwent any allopathic Treatment

1. Yes 2. No.

If yes specify the nature of the drug and treatment duration _____

**13. FAMILY HISTORY:**

Whether this problem runs in family?

1. Yes 2. No

If yes, mention the relationship of affected person(s)

1. _____
2. _____

**14. DIETARY HABITS :**

1. Pure vegetarian ☐
2. Non-Vegetarian ☐

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

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**PALAYAMKOTTAI, TIRUNELVELI – 627002**

**BRANCH – III SIRAPPU MARUTHUVAM**

TO EVALUATE THE CLINICAL EFFICACY OF SIDDHA HERBO MINERAL FORMULATION "**SANTHIRA PRAGASA MATHIRAI**" INTERNAL & "**SEMBAI THYLAM**" EXTERNAL IN "**KUMBA VATHAM**" (PERIARTHRITIS OF SHOULDER).

**FORM II AND II-A CLINICAL ASSESSMENT ON ENROLLMENT AND ON VISITS**

1. OP / IP No :
2. BED No :
3. SL. NO :
4. NAME :
5. AGE :
6. GENDER :
7. OCCUPATION :
8. SOCIAL STATUS :
9. DATE OF ADMISSION :
10. DATE OF DISCHARGE :
11. POSTAL ADDRESS :
12. COMPLAINTS & DURATION :
13. HISTORY OF PRESENT ILLNESS :
14. PAST HISTORY :
15. FAMILY HISTORY :

16. MENSTRUAL HISTORY (If Applicable):
17. **HABITS:**
    1. Smoker :
    2. Alcoholic :
    3. Tobbaco chewer :

4. Betel nut chewer :
5. Non-Vegetarian :
6. Drug addiction :

**18. GENERAL EXAMINATION:**

1. Body weight (Kg) :
2. Height (Cm) :
3. Body Temperature (F) :
4. Blood Pressure (mmHg) :
5. Pulse Rate (/min) :
6. Heart Rate (/min) :
7. Respiratory Rate (/min) :
8. Pallor :
9. Jaundice :
10. Clubbing :
11. Cyanosis :
12. Pedal Oedema :
13. Lymphadenopathy :
14. Jugular venous pulsation :

**19. CLINICAL EXAMINATION:**

**I. INSPECTION:**

1. Attitude :
2. Muscular spasm :
3. Muscle wasting – Proximal :
4. Muscle wasting – Distal :
5. Minor Joint Swelling :
6. Major Joint Swelling :
7. Nodules :
8. Deformity :

**II. PALPATION:**

1. Swelling :
2. Tenderness :
3. Joint Stiffness :
4. Muscle wasting :

5. Local heat :
6. Local Lymphadenopathy :
7. Pitting Oedema :
8. Nodules :

**III. MOVEMENTS:**

Restriction of joint movements

1. Neck : Full Partial
2. Shoulder :
3. Elbow joint :
4. Knee joint :
5. Ankle joint :
6. Hip joint :
7. Minor joints :

**IV. PAIN:**

1. Onset : Sudden : Gradual :
2. Early morning stiffness : Present : absent :
3. Nature of pain: Mild : Moderate : Severe:
4. Aggravating factor –Movements :
5. Relieving factor – rest :
6. Stiffness :
7. Tenderness :

**V. CLINICAL ASSESSMENT :**

1. Arthritis of three or more Joints :
2. Arthritis of hand joints :
3. Morning Stiffness :
4. Fever :
5. Anorexia :
6. Anaemia :
7. Spindle appearance of fingers :
8. Restricted movements :
9. Rheumatoid Nodules :
10. Numbness :

**20. EXAMINATION OF OTHER SYSTEMS:**

1. CVS :
2. RS :
3. CNS :
4. ABDOMEN :
5. GENITO – URINARY :

**EXAMINATION – SIDDHA ASPECTS**

**1. NILAM:**

1. Kurinji 2. Mullai 3. Marutham 4. Neithal 5. Paalai

**2. KAALAM:**

1. Kaar Kaalam 2. Koothir Kaalam 3. Munpani Kaalam
4. Pinpani Kaalam 5. Elavenir Kaalam 6. Mudhuvenir Kaalam

**3. YAAKKAI:**

| | | |
|---|---|---|
| 1. Vatham | 2. Pitham | 3. Kabam |
| 4. Vathapitham | 5. Pithavatham | 6. Kabavatham |
| 7. Vathakabam | 8. Pithakabam | 9. Kabapitham |

**4. GUNAM:**

1. Sathuvam 2. Rasatham 3. Thamasam

**5. KANMENDHIRIUM / KANMAVIDAYAM**

1. Kai :
2. Kaal :
3. Vaai :
4. Eruvaai :
5. Karuvaai :

**6. UYIR THATHUKKAL:**

**I. VATHAM:**

1. Piraanan :
2. Abaanan :
3. Viyaanan :
4. Uthaanan :
5. Samaanan :

6. Naagan :
7. Koorman :
8. Kirukaran :
9. Devathathan :
10. Dhananjeyan :

**II. PITHAM :**

1. Analagam :
2. Ranjagam :
3. Saathagam :
4. Aalosagam :
5. Praasagam :

**III. KABAM:**

1. Avalambagam :
2. Kilethagam :
3. Pothagam :
4. Tharpagam :
5. Santhigam :

**7. UDAL THAATHUKKAL:**

1. Saaram :
2. Senneer :
3. Oon :
4. Kozhuppu :
5. Enbu :
6. Moolai :
7. Sukkilam / Suronitham:

**8. ENVAGAI THERVUGAL:**

1. Naadi :
2. Sparisam :
3. Naa :
4. Niram :

5. Mozhi :
6. Vizhi :

7. Malam :
   i. Niram: ii. Thanmai: iii. Irugal: iv.Ilagal:
8. Moothiram :

**I. NEERKURI:**

a. Niram :
b. Manam :
c. Edai :
d. Nurai :
e. Enjal :

**II. NEIKURI:**

Vatha Neer : Pittha Neer : Kaba Neer :

Date :
Station:
Signature of the Investigator :
Signature of the Lecturer : **Signature of the HOD**

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**PALAYAMKOTTAI, TIRUNELVELI – 627002**

**BRANCH – III SIRAPPU MARUTHUVAM**

TO EVALUATE THE CLINICAL EFFICACY OF SIDDHA HERBO MINERAL FORMULATION "**SANTHIRA PRAGASA MATHIRAI**" INTERNAL & "**SEMBAI THYLAM**" EXTERNAL IN "**KUMBA VATHAM**" (PERIARTHRITIS OF SHOULDER).

**FORM III – LABORATORY INVESTIGATION**

1. BLOOD:
   1. TC : (Cells / Cumm)
   2. DC (%) : N : L : M : E :
   3. ESR (mm) : ½ hr : 1 hr :
   4. Hb :
   5. Blood Sugar : a) Fasting : b) Post Prandial :
   6. Renal function tests:
      Blood Urea: Serum creatinine:
   7. Lipid profile :
      HDL: LDL: VLDL:
      Total Cholesterol : TGL :
   8. Liver Function tests:
      Serum Bilirubin : Total Direct Indirect

**SPECIFIC INVESTIGATIONS**

RA factor :

ASO titre :

C-Reactive Protein :

SGOT :

SGPT :

Serum albumin & globulin :

Total protein :

**II. URINE:**

1. Albumin :
2. Sugar :
3. Epithelial cells :
4. Pus cells :
5. Red blood cells :
6. Casts / Crystals :

**III. MOTION:**

1. Ova :
2. Cyst :
3. Occult blood :
4. Pus cells :

**IV. X-RAY FINDINGS**

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

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## FORM IV A – CONSENT FORM

**CERTIFICATE BY INVESTIGATOR**

I certify that I have disclosed all the details about the study in the terms readily understood by the patient.

Signature _____

Date _____

Name _____

**CONSENT BY PATIENT**

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my body functions.

I am aware of my right to opt out of the trial at any time during the course of the trial without having to give the reasons for doing so.

I exercising my free power of choice, hereby give my consent to be included as a subject in the clinical trial of "SANTHIRA PRAGASA MATHIRAI" (Internal drug) and "CHITHIRAMOOLA ENNAI" (External drug) for the treatment of "KUMBA VATHAM" (PERIARTHRITIS OF SHOULDER)".

Place :

Date :

Signature :

Name :

Witness Signature:

Name :

**அரசினர் சித்த மருத்துவக் கல்லூரி மற்றும் மருத்துவமனை**

**பாளையங்கோட்டை**

**பட்டமேற்படிப்பு சிறப்பு மருத்துவத்துறை**

**"சந்திர பிரகாச மாத்திரை " மற்றும் "செம்பை தைலம்" இவற்றின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வு ஒப்புதல் படிவம் ஆய்வாளரால் சான்றளிக்கப்பட்டது.**

நான் இந்த ஆய்வைக் குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி : கையொப்பம்:

இடம் : பெயர்:

**நோயாளியின் ஒப்புதல்**

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும் மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறையைப் பற்றியும் தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றியும் திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல் எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன்.

நான் என்னுடைய சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டு கும்பவாதம் என்னும் நோய்க்கான சந்திர பிரகாச மாத்திரை மற்றும் செம்பை தைலம் ஆகியவற்றின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி : கையொப்பம்:

இடம் : பெயர் :

சாட்சிக்காரர் கையொப்பம்:

பெயர் :

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**FORM IV B – WITHDRAWAL FORM**

1. SL.NO : _____
2. OP / IP NO : _____
3. NAME : _____
4. RELIGION : H / C / M / O
5. AGE / GENDER : _____
6. OCCUPATION : _____
7. SOCIAL STATUS : _____
8. CONTACT NO : _____
9. DATE OF TRIAL COMMENCEMENT : _____
10. DATE OF WITHDRAWAL FROM TRIAL : _____
11. REASONS FOR WITHDRAWAL : _____
    - Long absence at reporting : Yes / No
    - Irregular treatment : Yes / No
    - Shift of locality : Yes / No
    - Increase in severity of symptoms : Yes / No
    - Development of severe adverse drug reactions: Yes / No

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

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Name of the Drug : SANTHIRA PRAGASA MATHIRAI

Drugs issued : (Mg / Gram)

Drugs returned : (Mg / Gram)

| **S. NO** | **DATE** | **DRUG TAKEN TIME** | |
|---|---|---|---|
| | | **MORNING / TIME** | **EVENING / TIME** |
| Day 1 | | | |
| Day 2 | | | |
| Day 3 | | | |
| Day 4 | | | |
| Day 5 | | | |
| Day 6 | | | |
| Day 7 | | | |
| Day 13 | | | |
| Day 14 | | | |
| Day 15 | | | |
| Day 16 | | | |
| Day 17 | | | |
| Day 18 | | | |
| Day 19 | | | |
| Day 25 | | | |
| Day 26 | | | |

| | | | |
|---|---|---|---|
| Day 27 | | | |
| Day 28 | | | |
| Day 29 | | | |
| Day 30 | | | |
| Day 31 | | | |
| Day 37 | | | |
| Day 38 | | | |
| Day 39 | | | |
| Day 40 | | | |

Date :

Station:

Signature of the Investigator :

Signature of the Lecturer : **Signature of the HOD**

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